UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

FWK HOLDINGS, LLC, KPH HEALTHCARE SERVICES, INC., d/b/a/ KINNEY DRUGS, INC., MEIJER, INC., and MEIJER DISTRIBUTION, INC., individually and on behalf of all others similarly situated, Plaintiffs, v. TEVA PHARMACEUTICALS INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., TEVA NEUROSCIENCE, INC., and TEVA SALES & MARKETING, INC. Defendants.	Civil Action No. _____ CLASS ACTION JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

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The plaintiffs, FWK Holdings, LLC, KPH Healthcare Services, Inc. d/b/a Kinney Drugs, Meijer, Inc., and Meijer Distribution, Inc. ("Plaintiffs"), on behalf of themselves and all others similarly situated, for their class action complaint against Teva Pharmaceuticals Industries, Ltd., Teva Pharmaceuticals USA, Inc., Teva Neuroscience, Inc., and Teva Sales & Marketing, Inc. (collectively, "Defendants" or "Teva"), allege, based on personal knowledge as to themselves and upon information and belief as to the other allegations, as follows:

I. INTRODUCTION

1. Copaxone® ("Copaxone") is Teva's injectable drug product indicated to reduce relapses in patients with relapsing-remitting multiple sclerosis, a condition characterized by inflammation of the insulating membranes surrounding nerve fibers in the central nervous system. Glatiramer acetate is the active ingredient in Copaxone. Teva received FDA approval for Copaxone in 1996 and launched shortly thereafter. From 2015 through 2017, Teva's Copaxone U.S. revenues exceeded $3 billion in each year.

2. Generic Copaxone market entry began in June 2015 and continued through February 2018:

Date	Manufacturer	Product
June 18, 2015	Sandoz	generic Copaxone 20mg
October 4, 2017	Mylan	generic Copaxone 20mg
October 4, 2017	Mylan	generic Copaxone 40mg
February 13, 2018	Sandoz	generic Copaxone 40mg

3. Despite the availability of these more affordable generic Copaxone products, Teva continued to dominate the market by unlawfully suppressing generic competition. It was not until the Department of Justice ("DOJ") filed its lawsuit against Teva for violations of the federal Anti-Kickback Statute on August 18, 2020 and the Committee on Oversight and Reform of the U.S.

House of Representatives ("House Committee") issued its report on September 30, 2020 (the "Staff Report") that Teva's multi-faceted monopolization scheme came to light.

4. As revealed by the Staff Report, Teva unlawfully suppressed generic competition for Copaxone by: (i) entering into exclusionary contracts with pharmacy benefits managers ("PBMs") and specialty pharmacies that barred generic Copaxone; (i) engaging in a coercive product switch to thwart generic competition; (iii) pursuing an aggressive "Dispense as Written" campaign fueled by misinformation about generic Copaxone; and (iv) paying illegal kickbacks and otherwise manipulating patient copays to boost sales of brand Copaxone. Through this unlawful scheme, Teva caused Plaintiffs and the Class (defined below) to purchase brand Copaxone despite the availability of more affordable generics, causing Plaintiffs and the Class to suffer overcharges on their brand Copaxone purchases which continue to the present day.

5. As revealed by the Staff Report, Teva suppressed generic competition in part by entering into exclusionary contracts, pursuant to which PBMs agreed to exclude generic Copaxone from their formularies and specialty pharmacies agreed to always dispense the brand product, even when the generic was prescribed.

6. Teva also engaged in a coercive product switch to prevent the automatic generic substitution that otherwise would have occurred, commenting internally that the new product was an "Opportunit[y]" to create a "Barrier to Generic entrance." Specifically, as generic Copaxone 20mg neared market entry, Teva launched a new 40mg dosage, a pursuit senior Teva scientists were "strongly against" because it had "no scientific rationale/value." Teva then switched the market to the new dosage by, *inter alia,* enlisting PBMs to lobby doctors to convert all patients to the 40mg and by tying rebates on Copaxone 20mg to the PBM's inclusion of Copaxone 40mg on the formulary. Within six months of generic entry, nearly 80% of patients had been converted to the 40mg dosage, thwarting the generic substitution that otherwise would have occurred.

7. When Mylan subsequently launched the first generic Copaxone 40mg (and second Copaxone 20mg), Teva responded by implementing an aggressive "Dispense as Written" campaign based in part on representing to doctors, without any scientific basis, that generic Copaxone was less effective than the brand product. Within four months of the launch of generic Copaxone 40mg, more than 77% of Copaxone 40mg prescriptions bore the notation "Dispense as Written," preventing generic substitution and foreclosing competition to a significant portion of the market.

8. Teva also paid millions of dollars in illegal kickbacks to charitable foundations with the purpose and understanding that the "donations" would be used to subsidize patients' out-of-pocket costs for brand Copaxone only, thereby driving up sales of the brand product. This price distortion was intended to, and succeeded in, suppressing competition. In a lawsuit recently filed against Teva, the DOJ alleges that this conduct violates the federal anti-kickback statute, 42 U.S.C. § 13320a-7b(b) (the "Anti-Kickback Statute") and resulted in Medicare paying out hundreds of millions of dollars in false claims.

9. Teva's anticompetitive scheme to suppress generic competition caused Plaintiffs and Class members to purchase brand Copaxone instead of more cost-effective generic Copaxone, causing them to suffer overcharges.

10. Plaintiffs and the Class have suffered overcharges on their Copaxone 20mg purchases, which began in June 2015, when the first generic Copaxone 20mg product became available, and continue through the present.

11. Plaintiffs and the Class have suffered overcharges on their Copaxone 40mg purchases, which began in October 2017, when the first generic Copaxone 40mg entered the market, and continue through the present.

12. Accordingly, Plaintiffs, individually and on behalf of a Class of those similarly situated, seek damages and all other appropriate relief for Teva's wrongdoing.

II. PARTIES

13. Plaintiff FWK Holdings, LLC ("FWK") is a limited liability company organized under the laws of the state of Illinois, with its principal place of business located in Glen Ellyn, Illinois. FWK is the assignee of the claims of the Frank W. Kerr Company, which, during the Class Period (defined below) purchased brand Copaxone directly from Teva at supracompetitive prices, when it otherwise would have purchased the more cost-effective generic products, but for Teva's anticompetitive conduct alleged herein, thereby suffering antitrust injury.

14. Plaintiff KPH Healthcare Services, Inc., d/b/a Kinney Drugs, Inc. ("KPH") is a corporation organized under the laws of the state of New York, with headquarters in Gouverneur, New York. KPH operates retail and online pharmacies in the Northeast under the name Kinney Drugs, Inc. KPH is the assignee of the claims of McKesson Corporation, which, during the class period, purchased brand Copaxone directly from Teva and suffered antitrust injury as a result of the anticompetitive conduct alleged herein.

15. The Assignment Agreement between McKesson and KPH executed on January 28, 2022 states that KPH purchases from McKesson the drug product Copaxone, described as "a brand-name drug manufactured and/or marketed by Teva Pharmaceuticals Industries Ltd., Teva Pharmaceuticals USA, Inc., Teva Neuroscience, Inc., and Teva Sales & Marketing, Inc.," and generic Copaxone products (including Glatopa®), described as "manufactured and/or marketed by Mylan Pharmaceuticals, Inc. and Sandoz Inc." Assignment Agreement ¶ A (January 28, 2022). The Teva entities, Mylan, and Sandoz are identified as "Manufacturers/Suppliers." *Id.* Pursuant to the Assignment Agreement, McKesson assigned and transferred to KPH "one hundred percent (100%) of all rights, title and interest in and to any antitrust cause of action it may have against Manufacturers/Suppliers and any other manufacturer or supplier wrongdoer(s) under the laws of the United States or of any state (a) so long as the cause of action is that the Manufacturers/Suppliers

unlawfully delayed or frustrated the sale of generic Copaxone and (b) only to the extent the cause of action arises from McKesson's purchases of brand and generic Copaxone that were subsequently resold to Customer during the period from November 1, 2013 through the date of this Assignment." *Id.* ¶ 1. The Assignment Agreement states that, "[f]or the avoidance of doubt, the sale of generic Copaxone includes the uptake of generic version(s) of Copaxone over brand Copaxone." *Id.*

16. In executing the Assignment Agreement, the intent of both KPH and McKesson was for McKesson to assign to KPH all antitrust claims McKesson had against the manufacturers and suppliers of brand and generic Copaxone for unlawfully delaying or frustrating the sale of generic Copaxone, including the delay in the uptake (that is, market penetration) of generic Copaxone over brand Copaxone, arising from McKesson's purchases of brand and generic Copaxone subsequently resold to KPH during the defined period.

17. In entering the Assignment Agreement, McKesson's and KPH's intent as to the period of damages was through the date on which the effects of Manufacturers/Suppliers' conduct ceases.

18. Plaintiffs Meijer, Inc. and Meijer Distribution, Inc., (collectively, "Meijer") are corporations organized under the laws of the state of Michigan, with their principal place of business located in Grand Rapids, Michigan. Meijer is the assignee of the claims of McKesson Corporation, which, during the class period, purchased brand Copaxone directly from Defendants at supra-competitive prices and suffered antitrust injury as a result of the anticompetitive conduct alleged herein. Meijer purchased brand Copaxone from McKesson in each year from 2015 to the present.

19. Defendant Teva Pharmaceuticals Industries, Ltd. ("Teva Ltd.") is a worldwide pharmaceutical company engaged in the development, manufacturing, marketing, and sale of

pharmaceutical products. Teva Ltd. is an Israeli company, having its principal place of business at 5 Basel Street, P.O. Box 3190, Petach Tikva, 49131, Israel.

20. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation, having its principal place of business at 400 Interpace Parkway #3, Parsippany, NJ 07054. Teva USA does business throughout the United States, including in this district.

21. Defendant Teva Neuroscience, Inc. ("Teva Neuroscience") is a Delaware corporation, having its principal place of business at 11100 Nall Ave, Overland Park, Kansas, 66211. Teva Neuroscience does business throughout the United States, including in this district.

22. Defendant Teva Sales & Marketing, Inc. ("Teva Sales") is a Delaware corporation, having its principal place of business at 11100 Nall Avenue, Overland Park, Kansas 66211. Teva Sales does business throughout the United States, including in this district.

23. Upon information and belief, Teva USA controls, directs, and supervises the sales and marketing activities of Teva Neuroscience and Teva Sales, as well as their employees.

24. Upon information and belief, Teva Ltd. controls, directs, and supervises the sales and marketing activities of Teva USA, Teva Neuroscience, and Teva Sales, as well as their employees.

25. Teva USA, Teva Neuroscience, and Teva Sales are subsidiaries of Teva Ltd.

III. JURISDICTION AND VENUE

26. This action alleges violations of Section 2 of the Sherman Act, 15 U.S.C. § 2, and Section 3 of the Clayton Act, 15 U.S.C. § 14, and seeks relief under Section 4 of the Clayton Act, 15 U.S.C. § 15(a), to recover threefold damages, costs of suit, and reasonable attorneys' fees for the injuries sustained by Plaintiffs and Class members resulting from Defendants' scheme to thwart generic competition in the United States in the market for glatiramer acetate injectable products. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a) and 15 U.S.C. § 15.

27. Venue is proper in this district pursuant to 15 U.S.C. §§ 15(a), 22 and 28 U.S.C. § 1391(b)-(d) because during the Class Period (defined below) Defendants resided, transacted business, were found, or had agents in this district and a substantial portion of the alleged activity affecting interstate trade and commerce discussed below has been carried out in this district.

28. Venue is appropriate within this district under 15 U.S.C. §§15(a) and 22 and 28 U.S.C. §1391(b), (c) and (d), because Defendants each transact business within this district and a substantial portion of the interstate trade and commerce, hereinafter described, is carried out in this district.

29. This Court has *in personam* jurisdiction over Defendants because they, either directly or through the ownership and/or control of their subsidiaries, *inter alia*: (a) transacted business throughout the United States, including in this district; (b) had and maintained substantial aggregate contacts with the United States as a whole, including in this district; or (c) were engaged in an illegal scheme that was directed at, and had a direct, substantial, reasonably foreseeable, and intended effect of causing injury to the business or property of persons and entities residing in, located in, or doing business throughout the United States, including in this district. Defendants also conduct business throughout the United States, including in this district, and have purposefully availed themselves of the laws of the United States.

30. By reason of the unlawful activities alleged herein, Defendants substantially affected commerce throughout the United States, causing injury to Plaintiffs and members of the Class. The Defendants, directly and through their agents, engaged in activities to suppress competition, drive up brand sales, and fix, raise, maintain, and/or stabilize the price of Copaxone in the United States, which unreasonably restrained trade and adversely affected the market for the direct sale and purchase of glatiramer acetate injectable products.

31. Defendants' unlawful conduct described herein adversely affected persons and entities in the United States who purchased branded Copaxone, including Plaintiffs and the members of the Class.

IV. REGULATORY AND ECONOMIC BACKGROUND

A. The regulatory structure for approval and substitution of generic drugs flows from the FDCA and the FDA and intersects with the patent framework.

32. Under the federal Food, Drug, and Cosmetic Act (FDCA),[1] manufacturers that create a new drug must obtain approval from the Food and Drug Administration (FDA) to sell the product by filing a New Drug Application (NDA).[2] An NDA must include specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.[3]

33. When the FDA approves a brand manufacturer's NDA, the manufacturer may list in *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the "Orange Book") certain kinds of patents that the manufacturer asserts could reasonably be enforced against a generic manufacturer that makes, uses, or sells a generic version of the brand drug before the expiration of the listed patents.[4] The manufacturer may list in the Orange Book within 30 days of issuance any patents issued after the FDA approved the NDA.[5] Valid and infringed patents may lawfully prevent generic competition, at least for a period, but manufacturers can abuse the system to use invalid or non-infringed patents to unlawfully delay generic competition.

34. The FDA relies completely on the brand manufacturer's truthfulness about patent validity and applicability because it does not have the resources or authority to verify the

[1] Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended in 21 U.S.C. § 301 *et seq.*).

[2] 21 U.S.C. §§ 301-392.

[3] 21 U.S.C. § 355(a), (b).

[4] For example, patents covering processes for making drug products may not be listed in the Orange Book.

[5] 21 U.S.C. § 355(b)(1), (c)(2).

manufacturer's patents for accuracy or trustworthiness. In listing patents in the Orange Book, the FDA merely performs a ministerial act.

1. Congress designed the Hatch-Waxman Amendments to the FDCA to encourage and hasten generic entry and reduce healthcare costs.

35. The FDCA's Hatch-Waxman Amendments, enacted in 1984, simplified regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs.[6] A manufacturer seeking approval to sell a generic version of a brand drug may instead file an Abbreviated New Drug Application (ANDA). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA and must show that the generic contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug and that it is bioequivalent, *i.e.*, absorbed at the same rate and to the same extent as the brand.

36. Drug products that the FDA considers therapeutically equivalent to the reference drug product are assigned an "A" code. This includes products for which "there are no known or suspected bioequivalence problems" (AA, AN, AO, AP, or AT, depending on how the drug is administered) and drug products for which "actual or potential bioequivalence problems have been resolved with adequate *in vivo* and/or *in vitro* evidence supporting bioequivalence" (AB). Injectable drugs that have been determined by the FDA to be therapeutically equivalent to the reference drug are designated AP-rated.

37. The FDCA and Hatch-Waxman Amendments operate on the principle that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity are therapeutically equivalent and may be substituted for one another.

[6] *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355).

38. Through the Hatch-Waxman Amendments, Congress sought to expedite the entry of less expensive generic competitors to brand drugs, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

39. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches and ushering in an era of historically high profit margins for brand pharmaceutical manufacturers. In 1983, before the Hatch-Waxman amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, revenues for brand and generic prescription drugs totaled $21.6 billion; by 2013, total prescription drug revenues had climbed to more than $329.2 billion, with generics accounting for 86% of prescriptions.[7] Generics are dispensed about 95% of the time when a generic form is available.[8]

2. The FDA may grant regulatory exclusivities for new drugs, but those exclusivities do not necessarily bar generic entry.

40. To promote a balance between new drug innovation and generic drug competition, the Hatch-Waxman Amendments also provide for exclusivities (or exclusive marketing rights) for new drugs. The FDA grants any such exclusivities upon approval of a drug if the sponsor and/or drug meet the relevant statutory requirements. Any such exclusivities for a drug are listed in the Orange Book, along with any applicable patents, and can run concurrently with the listed patents.

41. One such exclusivity, the New Chemical Entity (NCE) exclusivity, applies to products containing chemical entities never previously approved by the FDA either alone or in combination. If a product receives NCE exclusivity, the FDA may not accept for review any ANDA

[7] *See* IMS Institute for Healthcare Informatics, *Medicine Use and Shifting Costs of Healthcare: A Review of the Use of Medicines in the United States in 2013* 30, 51 (2014).

[8] *Id.* at 51.

for a drug containing the same active moiety for five years from the date of the NDA's approval, unless the ANDA contains a certification of patent invalidity or non-infringement, in which case an application may be submitted after four years.[9]

42. A drug product may also receive a three-year period of exclusivity if its sponsor submits a supplemental application (sNDA) that contains reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the sponsor that were essential to approval of the supplemental application. If this exclusivity is granted, the FDA may not approve an ANDA for that drug for three years from the date on which the supplemental application is approved.[10]

43. Regulatory exclusivities may not be absolute bars to generic entry. For example, some can be overcome by carving out information in the label or for other reasons.[11]

3. The first ANDA filer to issue a paragraph IV certification is entitled, once approved, to 180 days as the only ANDA generic on the market.

44. To obtain FDA approval of an ANDA, a manufacturer must certify that the generic will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications:

a. That no patent for the brand has been filed with the FDA (a paragraph I certification);

b. That any patent(s) for the brand has/have expired (a paragraph II certification);

c. That any patent(s) for the brand will expire on a particular date and the manufacturer does not seek to market its generic before that date (a paragraph III certification); or

d. That any patent(s) for the brand is/are invalid or will not be infringed by the generic manufacturer's proposed product (a paragraph IV certification).[12]

[9] 21 U.S.C. § 355(j)(5)(F)(ii); 21 C.F.R. § 314.108(b)(2).

[10] 21 U.S.C. § 355(j)(5)(F)(iv); 21 C.F.R. § 314.108(b)(2)(5).

[11] *See, e.g.*, 21 C.F.R. §§ 314.94(a)(8)(iv), 314.127(a)(7); 21 U.S.C. § 355a(o).

[12] 21 U.S.C. § 355(j)(2)(A)(vii).

45. If a generic manufacturer files a paragraph IV certification, a brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within forty-five days of receiving notification of the paragraph IV certification, the FDA will not grant final approval to the ANDA-filer (which would enable the manufacturer to market and sell its product) until the earlier of (i) the passage of two-and-a-half years, or (ii) the issuance of a decision by a court that the patent at issue is invalid or not infringed by the generic manufacturer's ANDA.[13] Until one of those conditions occurs, the FDA may only grant tentative approval, meaning the ANDA meets all regulatory requirements and is approvable but for the 30-month stay.

46. To encourage manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman Amendments grant the first paragraph IV generic manufacturer ANDA filer (first-filer) a 180-day exclusivity period to market the generic version of the drug; the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand drug during that time.[14] That is, when a first-filer files a substantially complete ANDA with the FDA and certifies that the unexpired patents listed in the Orange Book as covering the brand are either invalid or not infringed by the generic, the FDA cannot approve a later generic manufacturer's ANDA until that first-filer generic(s) has been on the market for 180 days.[15]

47. The 180-day window is often referred to as the first filer's six-month or 180-day exclusivity; this is a bit of a misnomer, though, because a brand manufacturer can launch an

[13] 21 U.S.C. § 355(j)(5)(B)(iii). This period is commonly called a 30-month Hatch-Waxman stay or 30-month stay. The brand/patent holder can choose to sue the generic after 45 days, including waiting until the generic has launched its product, but, in that event, the brand cannot take advantage of the 30-month stay of FDA approval, and must instead satisfy the showing required to obtain a preliminary injunction to prevent the generic launch.

[14] 21 U.S.C. § 355(j)(5)(B)(iv), (D).

[15] There is an exception: if the first-filer forfeits exclusivity. A first filer can forfeit its 180-day exclusivity by, for example, failing to obtain tentative approval from the FDA for its ANDA within 30 months of filing its ANDA.

authorized generic (AG) at any time, manufacturing its AG in accordance with its approved NDA for the branded product but selling at a lower price point.

48. A first filer who informs the FDA it intends to wait until all Orange Book-listed patents expire before marketing its generic does not get a 180-day exclusivity period. Congress created this 180-day period to incentivize generic manufacturers to challenge weak or invalid patents or to invent around such patents by creating non-infringing generics.

4. Patents are not bulletproof.

49. The existence of one or more patents purporting to cover a drug product does not guarantee a monopoly. Patents are routinely invalidated or held unenforceable, either upon reexamination or in *inter partes* proceedings by the U.S. Patent and Trademark Office (PTO), by court decision, or by jury verdict. A patent holder always bears the burden of proving infringement.

50. One way that a generic can prevail in patent infringement litigation is to show that its product does not infringe the patent (and/or that the patent holder cannot meet its burden to prove infringement). Another is to show that the patent is invalid or unenforceable.

51. A patent is invalid or unenforceable when: (i) the disclosed invention is anticipated and/or obvious in light of earlier prior art; (ii) its claims are indefinite, lack sufficient written description, or fail to properly enable the claimed invention; (iii) an inventor, an inventor's attorney, or another person involved with the application, with intent to mislead or deceive the PTO, fails to disclose material information known to that person to be material, or submits materially false information to the PTO during prosecution; and/or (iv) when a later acquired patent is not patentably distinct from the invention claimed in an earlier patent (and no exception, such as the safe harbor, applies).

52. In these circumstances, the PTO's decision to issue a patent does not substitute for a fact-specific assessment of (i) whether the applicant made intentional misrepresentations or

omissions on which the PTO relied in issuing the patent, and (ii) whether a reasonable manufacturer in the patent holder's position would have a realistic likelihood of succeeding on the merits of a patent infringement suit.

53. As a statistical matter, if the parties litigate a pharmaceutical patent infringement suit to a decision on the merits, it is more likely that a challenged patent will be found invalid or not infringed than upheld. The FTC reports that generics prevailed in 73% of Hatch-Waxman patent litigation cases resolved on the merits between 1992 and 2002.[16] An empirical study of all substantive decisions rendered in every patent case filed in 2008 and 2009 similarly reports that when a generic challenger stays the course until a decision on the merits, the generic wins 74% of the time.[17]

54. If a generic manufacturer successfully defends against the brand's infringement lawsuit—either by showing that its ANDA does not infringe any asserted patents and/or that any asserted patents are invalid or unenforceable—the generic may enter the market immediately upon receiving approval from the FDA.

5. The Biologics Price Competition and Innovation Act likewise allows for approval of biosimilar drugs and enables competition with their biologic counterparts.

55. Biologics are not new; they include vaccines, first developed in the late eighteenth century. But technological advances in the past few decades have resulted in more biologics coming to market than ever before.

56. The approval process for a new biologic drug is also regulated by the FDCA and is similar to that for the brand name version of a small molecule drug. A manufacturer of a biologic

[16] FTC, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* vi-vii (2002), *available at* https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf (last accessed February 22, 2022).

[17] John R. Allison, Mark A. Lemley & David L. Schwartz, *Understanding the Realities of Modern Patent Litigation*, 92 TEX. L. REV. 1769, 1787 (2014) ("[P]atentees won only 164 of the 636 definitive merits rulings, or 26%," and "that number is essentially unchanged" from a decade ago).

may market the drug only if the FDA has licensed it pursuant to either of two review processes set forth in 42 U.S.C. § 262. The pathway for approval for new biologics is set forth in 42 U.S.C. § 262(a). Under that subsection, the drug manufacturer submits a Biologic License Application ("BLA"), which must include data similar to that included in an NDA; the FDA may license a new biologic if, among other things, the manufacturer demonstrates that it is "safe, pure, and potent."[18]

57. The statute also prescribes an alternative, abbreviated route for FDA approval of biosimilars, set forth in 42 U.S.C. § 262(k), which was enacted as part of the Biologics Price Competition and Innovation Act of 2009 ("BPCIA").[19] While the first approved version of a small molecule drug is commonly known as the "brand name" drug, the BPCIA refers to the first approved version of a biologic as the "reference" biologic. Biosimilar versions of biologic products are in some sense analogous to generic versions of brand name small molecule drugs.

58. However, the biologics/biosimilars regulatory system differs from that governing small molecule drugs in certain key respects. Because biologics "are derived from living cells, biologics can never be exactly reproduced or copied like [traditional] generics," biosimilars must undergo a more rigorous and expensive process than generic drugs to receive FDA approval. A biosimilar manufacturer must show that its product is "highly similar" to the reference product and that there are no "clinically meaningful differences" between the two in terms of "safety, purity, and potency."

59. Even once a biosimilar receives FDA-approval, it will not be automatically substitutable for the reference biologic product. Unlike generic drugs, the biosimilar must undergo a separate interchangeability determination before it will be considered substitutable. The FDA has made only two such "interchangeability" determinations to date, both of which occurred in 2021.

[18] 42 U.S.C. § 262(a)(2)(C)(i)(I).

[19] 124 Stat. 808.

60. In sum, while biosimilars are in some ways analogous to generic drugs, there are additional hurdles a biosimilar must overcome before it will be deemed automatically substitutable for the reference biologic product.

6. Misuse of citizen petitions delays FDA approval of generic drugs.

61. Section 505(j) of the Food, Drug and Cosmetic Act creates a mechanism by which a person may file a petition with the FDA requesting, among other things, that the agency take, or refrain from taking, any form of administrative action. This mechanism is commonly referred to as a "citizen petition."

62. Citizen petitions provide a forum for individuals to express and support their genuine concerns about safety, scientific, or legal issues regarding a product any time before, or after, its market entry. Other than the form it should take, the regulations place no restrictions on the subject matter of a citizen petition.

63. The FDA regulations concerning citizen petitions require the FDA Commissioner to respond to each citizen petition within 180 days of receipt. That response may be to approve the request in whole or in part or deny the request. The Commissioner also may provide a tentative response with an estimate on a time for a full response.

64. Reviewing and responding to citizen petitions is a resource-intensive and time-consuming task because, no matter how baseless a petition may be, the FDA must research the petition's subject, examine scientific, medical, legal, and sometimes economic issues, and coordinate internal agency review and clearance of the petition response. These activities strain the FDA's limited resources, and lengthy citizen petitions can delay the FDA approval of generic products even if those petitions ultimately are found to lack any reasonable evidentiary, regulatory, statutory, or scientific basis.

65. A citizen petition may be filed to request that the FDA take action regarding drug approval requirements, including those involving generic drugs. To successfully move the FDA to grant this type of request, the petition must include supportive, clinically meaningful data and the requested relief must be consistent with the Hatch-Waxman statutory and regulatory framework and within the power of the FDA to grant.

66. Abusive and anticompetitive citizen petitions have become an increasingly common problem in the last several years as brand name companies have sought to compensate for dwindling new product pipelines. In such cases, citizen petitions have been filed with respect to ANDAs that have been pending for a year or more, long after the brand name manufacturer received notice of the ANDA filing, delaying the approval of the generic product while the FDA evaluates the citizen petition.

67. Delaying generic competition is a lucrative strategy for an incumbent manufacturer. Given the marketplace's preference for generic products over brand products, the cost of filing an improper citizen petition may be trivial compared to the value of securing even a few months delay in a generic rival's entry into the market.

68. Even the FDA, which is often hesitant to comment on existing law, has at times spoken out against the current citizen petition process. Former FDA Chief Counsel Sheldon Bradshaw noted that in his time at the agency he had "seen several examples of citizen petitions that appear designed not to raise timely concerns with respect to the legality or scientific soundness of approving a drug application but rather to try to delay the approval simply by compelling the agency to take the time to consider arguments raised in the petition whatever their merits and regardless of whether or not the petitioner could have made those very arguments months and months before."

69. The FDA continues to have serious concerns about the abuse of the citizen petition process for anticompetitive purposes and noted in a 2020 report to Congress that "the Agency

continues to be concerned that section 505(q) does not discourage the submission of petitions that are intended primarily to delay the approval of competing drug products and do not raise valid scientific issues."[20]

70. It is the practice of the FDA, well known in the pharmaceutical industry, to withhold ANDA approval until after its consideration of and response to a citizen petition was complete. On this subject, Gary Buehler, a former Director of the Office of Generic Drugs, acknowledged that "[i]t is very rare that petitions present new issues that CDER [Center for Drug Evaluation and Research] has not fully considered, but the Agency must nevertheless assure itself of that fact by reviewing the citizen petitions."[21]

B. A-rated generics quickly and dramatically drive down prices for purchasers.

71. Generic versions of brand drugs contain the same active ingredient(s) as the brand name drug and are determined by the FDA to be just as safe and effective as their brand counterparts. Because the brand and its A-rated generics are essentially commodities that cannot be therapeutically differentiated, the primary basis for competition between a brand product and its generic version, or between multiple generic versions, is price.

72. Without A-rated generics in the market, the manufacturer of a brand drug has a monopoly—every sale of the product, and the accompanying profit, benefits the brand manufacturer. Without A-rated generic competition, brand manufacturers can, and routinely do, sell their drug for far more than the marginal cost of production, generating profit margins above 70%

[20] FDA, *Twelfth Annual Report on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2019* (2020), available at www.fda.gov/media/143518/download (last accessed February 22, 2022).

[21] Statement of Gary Buehler, R.Ph, Director of the Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, before the Special Committee on Aging, United States Senate, Hearing on Improving Access to Generic Drugs (July 20, 2006), available at https://www.aging.senate.gov/imo/media/doc/hr161gb.pdf (last accessed February 22, 2022).

while making hundreds of millions of dollars in sales. The ability to command these kinds of profit margins is what economists call market power.

73. When generic entry occurs, the brand manufacturer loses most of the unit sales; the generic manufacturer sells most of the units, but at drastically reduced prices, delivering enormous savings to drug purchasers. When multiple generics compete in the market, that competition drives prices down to near the marginal cost of production. This competition ends the brand manufacturer's market power and delivers enormous savings to drug purchasers. Competition converts what formerly were excess profits into purchaser savings.

1. The first A-rated generic is priced below the brand, driving sales to the generic.

74. Experience and economic research show that the first generic manufacturer to market its product prices it below the prices of its brand counterpart.[22] Every state either requires or permits that a prescription written for the brand be filled with an A-rated generic. Thus, the first generic manufacturer almost always captures a large share of sales from the brand. At the same time, there is a reduction in the average price paid for the drug at issue (brand and A-rated generic combined).

75. During the 180-day exclusivity period, the first filer is the only ANDA-approved generic manufacturer on the market. In the absence of competition from other generics, a first-filer generic manufacturer generally makes about 80% of all the profits that it will ever make on the

[22] FTC, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact* ii-iii, vi, 34 (2011) ("FTC 2011 AG Study"), available at https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf" (last accessed February 22, 2022); FTC, *Pay-For-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (2010) ("FTC Pay-for-Delay Study"), available at https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf (last accessed February 22, 2022).

product during that 180-day exclusivity period, a significant incentive for getting to market as quickly as possible.

76. Once generic competition begins, it quickly captures sales of the corresponding brand drug, often 80% or more of the market within the first six months after entry. (This percentage erosion of brand sales holds regardless of the number of generic entrants.) For blockbuster drugs, such as Copaxone, generic market share after one year is often higher than 90%.

2. Later generics drive prices down further.

77. Once additional generic competitors enter the market, the competitive process accelerates, and multiple generic manufacturers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs.[23] In a recent study, the Federal Trade Commission (FTC) found that on average, within a year of generic entry, generics had captured 90% of corresponding brand sales and (with multiple generics on the market) prices had dropped 85%.[24]

78. According to the FDA and the FTC, the greatest price reductions are experienced when the number of generic competitors goes from one to two. The discount from the brand price typically increases to between 50% and 80% (or more) when there are multiple generic competitors on the market for a given brand. Consequently, the launch of a generic usually results in significant cost savings for all drug purchasers: "[a]lthough generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price.

[23] *See, e.g.*, Tracy Regan, *Generic Entry, Price Competition, and Market Segmentation in the Prescription Drug Market*, 26 INT'L J. INDUS. ORG. 930 (2008); Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 NEW ENG. J. MED. 1993 (2007); Patricia M. Danzon & Li-Wei Chao, *Does Regulation Drive Out Competition in Pharmaceutical Markets?*, 43 J.L. & ECON. 311 (2000).

[24] *See* FTC Pay-for-Delay Study.

According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics."[25]

79. Generic competition enables all purchasers of a drug to (i) purchase generic versions of the drug at substantially lower prices, and/or (ii) purchase the brand at a reduced price. These competitive effects are known and reliable: brand sales decline to a small fraction of their level before generic entry and, as a result, brand manufacturers view competition from generics as a grave threat to their bottom lines.

80. Until a generic version of a brand drug enters the market, however, there is no FDA-approved bioequivalent drug to substitute for and compete with the brand, leaving the brand manufacturer to continue to profitably charge supracompetitive prices. Recognizing that generic competition will rapidly erode their brand sales, brand manufacturers seek to extend their monopoly for as long as possible, sometimes resorting to illegal means to delay or prevent generic competition.

C. Role of PBMs and Specialty Pharmacies

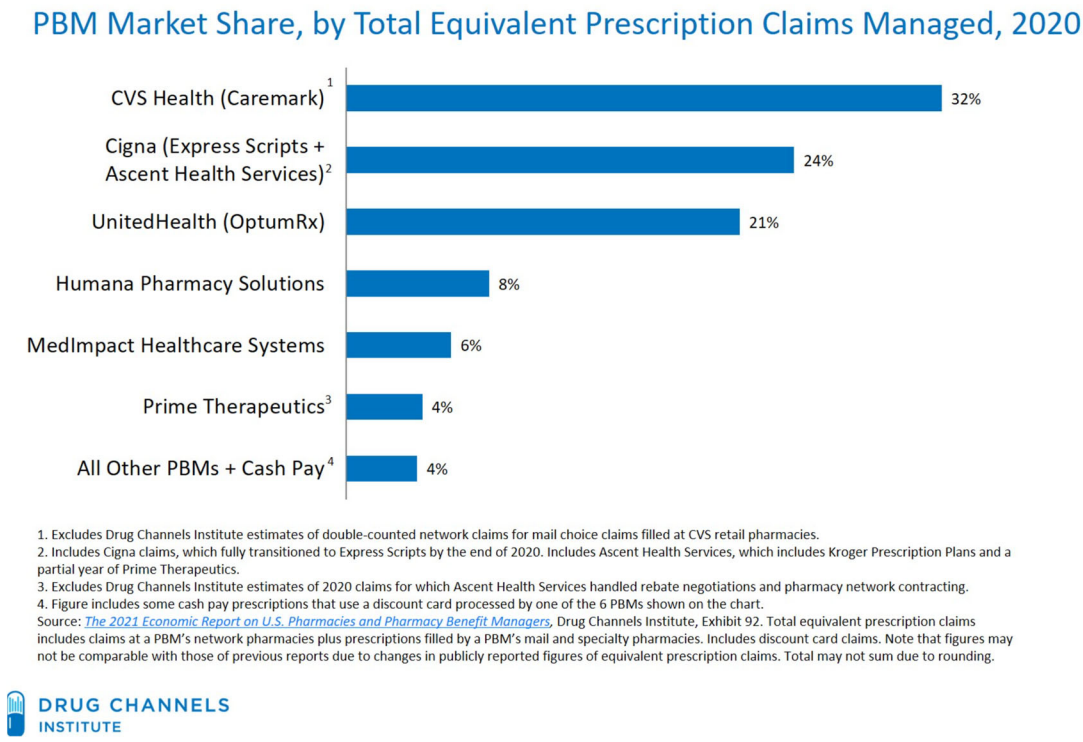
81. PBMs are third party entities that manage prescription drug benefits on behalf of their clients, which include health insurance companies, self-funded health plans, large companies, and governmental entities. PBMs create pharmacy networks. This includes mail order and specialty pharmacies, in addition to "brick and mortar" pharmacies. Many mail-order and specialty pharmacies are either owned by a PBM or share common ownership with a PBM.

82. Another major role of the PBM is to create and maintain a drug formulary for the PBM's clients. A formulary is a list of prescription drugs for which the health plan will reimburse pharmacies on behalf of the plan's members. The purpose behind the drug formulary is to provide quality care using the most cost-effective options. If a drug is not included on a formulary, the

[25] *See* "What Are Generic Drugs?," FDA (Aug. 24, 2017), *available at* https://www.fda.gov/drugs/generic-drugs/what-are-generic-drugs (last accessed February 22, 2022).

health plan generally will not cover the cost of the drug. Thus, if a doctor prescribes a drug that is not on the formulary, the patient will be required to pay the entire cost of the drug out-of-pocket.

83. The PBM market is highly concentrated. Indeed, just three PBMs comprise more than 75% of the market:[26]



84. In sum, through their control of formularies and pharmacy networks, PBMs have a prominent role in determining what drugs will be accessible to patients and at what cost. The PBMs' decisions may be influenced by drug manufacturers' rebating strategies, which raises special concerns where rebates are used by a monopolist to foreclose (rather than promote) competition.

V. BACKGROUND FACTS

85. In this section, Plaintiffs provide: (i) a brief history of Copaxone; (ii) the timeline of generic entry; (iii) an overview of Teva's efforts to delay generic entry and prevent generic

[26] Adam Fein, *The Top Pharmacy Benefit Managers of 2020: Vertical Integration Drives Consolidation*, Drug Channels (April 6, 2021), available at https://www.drugchannels.net/2021/04/the-top-pharmacy-benefit-managers-pbms.html (last accessed February 22, 2022).

substitution by manipulating the regulatory framework; and (iv) a summary of Teva's illegal conduct regarding Copaxone in foreign jurisdictions. The factual allegations set forth in this section (*i.e.,* Section V - "Background Facts") are included to provide important context for Plaintiffs' central allegation that, following generic entry in June 2015, Teva engaged in an unlawful scheme to suppress generic competition and drive up brand sales, as described more fully in Section VI, *infra.*

A. Since launching in 1997, Teva has made billions of dollars on Copaxone.

86. Approximately one million Americans suffer from multiple sclerosis, an incurable, often progressive, life-altering disease that afflicts the central nervous system. Those with multiple sclerosis may experience a wide range of symptoms, including weakness, numbness, tremors, loss of vision, blurry vision, slurred speech, fatigue, and dizziness.

87. The vast majority—approximately 85%—of those diagnosed with MS are diagnosed with relapse-remitting MS ("RRMS"), a condition characterized by inflammatory attacks on the layers of insulating membranes surrounding nerve fibers in the central nervous system. Copaxone is Teva's injectable drug product with the active ingredient glatiramer acetate indicated for reduction of the frequency of relapses in patients with RRMS.

88. Copaxone received FDA approval in December 1996 in the form of a 20mg vial. In February 2002, the FDA approved Copaxone 20mg for daily injection. Teva obtained nine patents claiming the Copaxone 20mg product, including the drug substance itself, pharmaceutical compositions comprising Copaxone, methods of treating multiple sclerosis using Copaxone, and methods of making Copaxone. Seven of these patents were listed in the Orange Book with an expiration date of May 24, 2014. The other two patents were not listed in the Orange Book because they only claimed processes for manufacturing Copaxone.

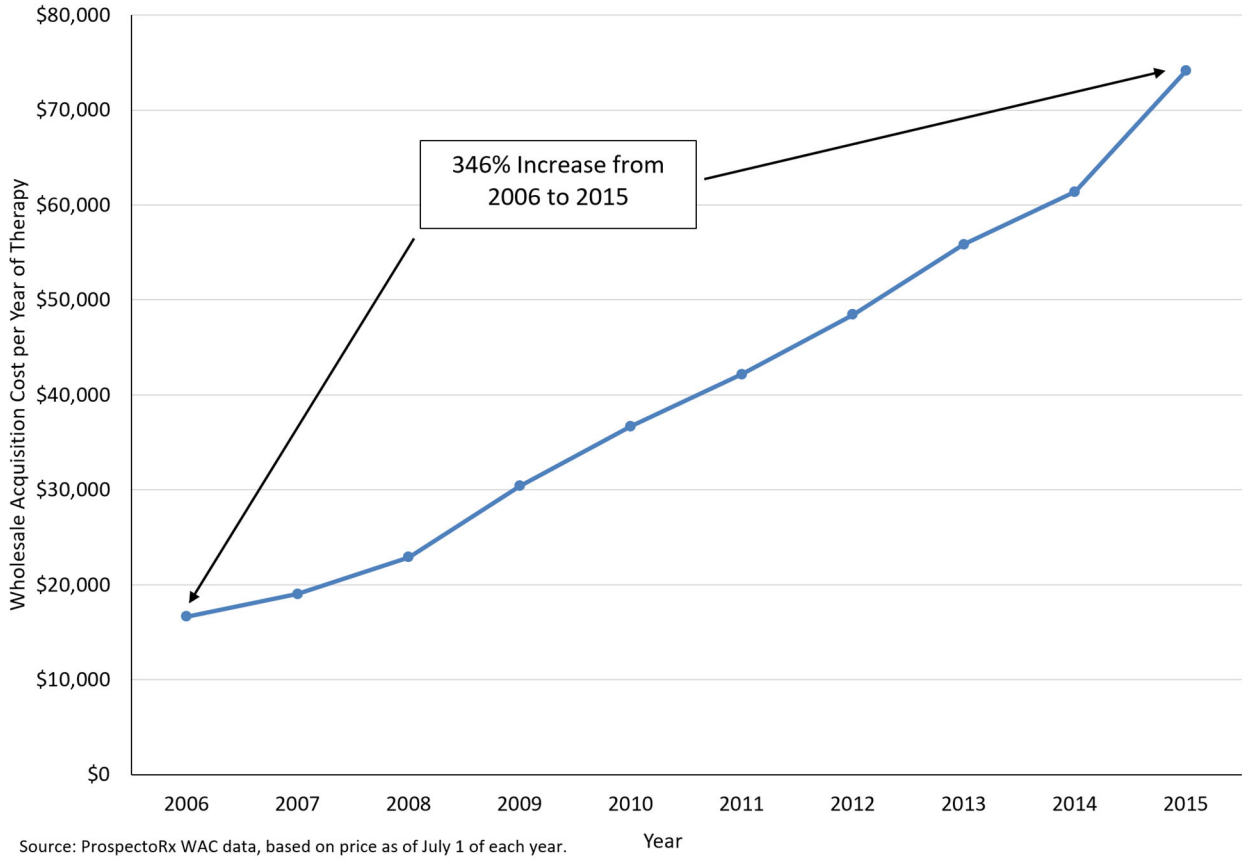
89. In 2013, Teva submitted a supplemental New Drug Application for a 40mg dosing strength of Copaxone to be administered three times per week. The FDA approved Copaxone 40mg

on January 28, 2014. Teva eventually obtained five patents that were listed in the Orange Book for Copaxone 40mg with an expiration date of August 19, 2030.

90. Teva has collected more than $34 billion in Copaxone net U.S. revenue since launching the drug. In 2016 alone (the first full year following generic entry), Teva's net U.S. revenue for Copaxone was $3.3 billion. In recent years, Copaxone accounted for approximately one-fifth of Teva's North American net revenues.

91. On December 10, 2021, the U.S. House of Representatives Committee on Oversight and Reform issued a report entitled "Drug Pricing Investigation – Majority Staff Report" that analyzed drug manufacturers' price increases, including Teva's price increases on Copaxone. According to the report, Teva has imposed more than twenty-five price hikes on Copaxone, increasing the price to $85,400/year, representing an 825% price increase since the product first launched. Over the period 2006-2015 alone, Teva increased the price of Copaxone 20mg by more than three-fold:

Figure 1: Wholesale Acquisition Cost per Year of Therapy, Copaxone 20 mg, 2006-2015



Source: ProspectoRx WAC data, based on price as of July 1 of each year.

B. Multiple generic manufacturers have sought to bring generic Copaxone to market.

1. Sandoz brought generic versions of the 20mg and 40mg to market in 2015 and 2018, respectively.

92. On or about December 27, 2007, Sandoz submitted ANDA No. 090218 for generic Copaxone 20mg to the FDA. On or about July 10, 2008, Sandoz sent a Paragraph IV notice letter to Teva asserting that the patents listed in the Orange Book for Copaxone 20mg were invalid or not infringed by Sandoz's ANDA product.

93. On or about February 14, 2014, Sandoz submitted ANDA No. 206921 for generic Copaxone 40mg to the FDA. On or about August 27, 2014, Sandoz sent a Paragraph IV notice letter to Teva asserting that the '250 and '413 patents were invalid or not infringed by Sandoz's

ANDA product. Sandoz subsequently sent similar Paragraph IV notice letters to Teva with respect to the '302 and '776 patents.

94. On April 16, 2015, the FDA approved Sandoz's ANDA for its generic Copaxone 20mg product.

95. On June 18, 2015, Sandoz launched its generic Copaxone 20mg product, marketed as Glatopa® ("Glatopa"). At the time of launch, Glatopa was the first generic Copaxone product available at 20mg strength.

96. On February 12, 2018, the FDA approved Sandoz's generic Copaxone 40mg product. On February 13, 2018, Sandoz launched generic Copaxone 40mg product. At launch, Sandoz's was the second generic Copaxone 40mg product to enter the market.

2. Mylan brought generic versions of both dosages to market in 2017.

97. On June 26, 2009, Mylan submitted ANDA No. 091646 for generic Copaxone 20mg to the FDA. On or about September 16, 2009, Mylan sent a Paragraph IV notice letter to Teva asserting that the patents listed in the Orange Book for Copaxone 20mg were invalid or not infringed by Mylan's ANDA product.

98. On or about February 12, 2014, Mylan submitted ANDA No. 206936 for generic Copaxone 40mg to the FDA. On or about August 28, 2014, Mylan sent a Paragraph IV notice letter to Teva asserting that the '250 and '413 patents were invalid or not infringed by Mylan's ANDA product. Sandoz subsequently sent similar Paragraph IV notice letters to Teva with respect to the '302 and '776 patents.

99. On October 3, 2017, the FDA approved Mylan's ANDAs for the 20mg and 40mg generic Copaxone products.

100. On October 4, 2017, Mylan launched its generic Copaxone 20mg and 40mg products. Mylan's generic Copaxone 40mg product was the first generic Copaxone product available

in the United States for 3-times-a-week injection that was an AP-rated substitute for Teva's 40mg Copaxone product. At launch, Mylan's generic Copaxone 20mg product was the second AP-rated substitute for Teva's 20mg Copaxone product in the United States market.

3. Additional generic manufacturers filed ANDAs but have not received FDA approval.

101. Other generic manufacturers, including Dr. Reddy's Laboratories Inc. ("Dr. Reddy's"), Synthon Pharmaceuticals, Inc. ("Synthon"), and Amneal GmbH ("Amneal"), have filed ANDAs for generic Copaxone 40mg, but these ANDAs have not yet received final approval from the FDA.

C. Teva engaged in extensive anticompetitive conduct to prevent generic competition.

102. Although generic manufacturers did eventually succeed in bringing generic Copaxone to market, Teva engaged in extensive efforts to block and otherwise delay generic entry. In describing this conduct, a federal court pointedly stated: "In 1995, Teva submitted an NDA for Copaxone, which FDA approved on December 20, 1996. . . . **Since that time, Teva has pursued every available avenue to prevent other glatiramer acetate products from coming to market**." *Teva Pharmaceuticals USA, Inc. v. United States Food and Drug Administration,* 514 F.Supp.3d 66, 81 (D.D.C. 2020) (emphasis added). Teva's efforts to prevent generic entry included engaging in sham patent litigation, filing numerous citizen petitions, and pursuing a baseless lawsuit against the FDA to have Copaxone regulated as a biologic.

1. Teva attempted to delay entry of generic Copaxone 40mg by engaging in sham patent litigation.

103. Following the launch of Copaxone 20mg in 1997, Teva enjoyed a period of market exclusivity afforded by its patents, which ended in May 2014.

104. Following the end of Teva's period of exclusivity, generics entering the market should have quickly gained market share, driving prices down by 85% or more within the first year.

To prevent this, in 2014, Teva began switching patients to Teva's new, three-times-weekly 40mg Copaxone product, which it sought to protect from generic competition by obtaining patents on the three-times-weekly dosing frequency.

105. The patents claiming the 40mg formulation and dosing regimen on their face protected Copaxone 40mg from generic competition until August 2030. Teva knew that it would not win in patent litigation over those patents, because the patents were invalid as obvious. Indeed, Teva's own submissions to the FDA reveal that Teva believed the three times weekly dosing regimen was obvious. For example, in December 2009, Teva submitted a clinical protocol to the FDA, in which Teva stated that, after finding the 40mg and 20mg dosage to be equally effective: "the natural next step [was] to reduce the dosing regimen of [Copaxone] and find the optimal regimen that [would] improve the convenience of treatment and reduce the burden and adverse events associated with daily subcutaneous injections."

106. Nevertheless, in an effort to block generic entry for Copaxone 40mg, Teva obtained the dosage frequency patents, which it listed in the Orange Book, and then filed baseless patent litigation against ANDA filers asserting those patents were infringed. Specifically, between 2014 and 2017, Teva sued Mylan, Sandoz (and Sandoz's commercialization partner Momenta Pharmaceuticals, Inc.), Dr. Reddy's, Synthon (and Synthon's commercialization partner Pfizer Inc.), and Amneal for infringement of the '250, '413, '302, and '776 patents (all dosage frequency patents) in relation to the generic manufacturers' ANDA applications.

107. Every tribunal to review Teva's 40mg three-times-a-week patents, including the District Court, PTAB, and Federal Circuit, found the dosage regimen obvious over the prior art. The district court concluded that Teva's 40mg three-times-a-week patents were "**nothing more than 'life-cycle management'—an attempt to continue to monopolize a multi-billion-dollar market for a blockbuster drug."**

108. Teva filed the patent lawsuits without regard to the merits of the validity or infringement claims and instead did so for the purpose of delaying generic approval, and therefore generic entry. Teva has thus used sham patent litigation against its generic competitors as an anticompetitive weapon to try to delay generic competition.

2. Teva filed a series of meritless citizen petitions over a seven-year period.

109. From 2008 to 2015, Teva filed eight citizen petitions with the FDA, seeking to block approval of ANDAs for generic Copaxone. Specifically, Teva's citizen petitions requested that the FDA deviate from the well-established ANDA approval process and refuse to approve any generic version of Copaxone unless it had undergone a full set of clinical trials.

110. If these requests had been granted, competitors would have been barred from using the normal routes for generic drug approval.

111. Each of Teva's eight citizen petitions was denied or withdrawn. In response to the denial of one of its citizen petitions, Teva sued the FDA and sought to "bar[] FDA from approving any application for a putative generic version of Copaxone® that does not comply with the conditions requested in Teva's citizen petition." That request was also denied, and the case dismissed.

112. Ironically, Teva has defended itself in the face of these serial filings and subsequent denials (in a separate suit alleging *inter alia,* racketeering and consumer fraud) by arguing "citizen petitions are almost never granted." Teva is correct that citizen petitions are "almost never granted," begging the question: Why did Teva file eight of them?

113. It is widely known throughout the pharmaceutical industry that the FDA will postpone approval of an ANDA until any related citizen petitions are resolved. Indeed, it was not until April 16, 2015, the same day that the last of Teva's citizen petitions was denied, that the first generic Copaxone product was approved. Teva's flurry of citizen petitions caught the attention of

antitrust scholar Michael Carrier, who described them as "a particularly glaring example of a company's aggressive use of the citizen petition process."

3. In March 2020, Teva filed a lawsuit against the FDA erroneously alleging that Copaxone should be regulated as a biologic.

114. As discussed above, the Biologics Price Competition and Innovation Act or BPCIA governs biologics and biosimilars. By March 23, 2020, the FDA was required to identify the pharmaceutical products that should be transitioned to biological product status. On March 24, 2020, the day following this deadline, Teva filed a lawsuit against the FDA alleging that the agency's denial of Teva's request to transition Copaxone to biologic product status was a violation of federal law.

115. Teva's motivation was clear. The automatic substitution laws that apply to generic drugs do not apply to biosimilars. Moreover, a biosimilar cannot be substituted for a biologic unless and until the FDA has made a separate, additional determination regarding "interchangeability." At the time Teva filed its lawsuit against the FDA, the FDA had not made this interchangeability determination for any product. Thus, if Teva had prevailed in its lawsuit, a pharmacist would have been prevented from dispensing a generic Copaxone product unless it had been specifically prescribed.

116. On December 31, 2020, the district court denied Teva's motions for summary judgment and granted the motions for summary judgment filed by the FDA and by the intervenor-defendants, Mylan, and Sandoz. In its decision, the court made clear its view that Teva's lawsuit was nothing more than "**yet another effort [by Teva] to stifle Copaxone competitors**."

D. Teva's conduct is part of a global campaign to exclude generic competition and drive up brand Copaxone sales.

117. On March 4, 2021, the European Commission ("EC") announced that it "has opened a formal antitrust investigation to assess whether the pharmaceutical company Teva has

illegally delayed the market entry and uptake of medicines that compete with its blockbuster multiple sclerosis drug Copaxone." The EC further explained that, "[i]f proven, Teva's behaviour may amount to an abuse of dominant position. . . ." According to the EC, this "is the Commission's first formal investigation into potential abuses relating to the misuse of patent procedures and exclusionary disparagement of competing products in the pharmaceutical industry."

118. Teva also pled guilty to violating the Foreign Corrupt Practices Act ("FCPA") and paid approximately $520 million in criminal and civil penalties to settle claims that Teva bribed medical professionals and government officials in Russia, Ukraine, and Mexico to drive up Copaxone sales. This is the largest ever criminal penalty imposed against a pharmaceutical company for FCPA violations.

VI. FACTS GIVING RISE TO PLAINTIFFS' CLAIM FOR RELIEF

119. Following generic entry, Teva has continued to dominate the market for Copaxone and its generic equivalents by illegally suppressing competition and frustrating generic uptake. Teva's unlawful monopolization scheme includes: (i) engaging in a coercive product switch; (ii) entering into exclusionary contracts with PBMs that blocked generic Copaxone at the formulary level and by specialty pharmacies; (iii) launching an aggressive dispense as written campaign based on untrue statements about generic Copaxone; and (iv) paying illegal kickbacks and manipulating commercial copays to drive up brand sales. Although a brand manufacturer's market share typically falls to 10% or less within one year of generic entry, Teva's exclusionary scheme enabled it to maintain a majority of the Copaxone market for years following generic entry.

A. Teva thwarted generic competition by switching the market from 20mg to 40mg Copaxone.

120. Drug manufacturers can and do bring new products, including changes to existing drugs, to market without giving rise to liability under the antitrust laws. However, drug manufacturer conduct comes under scrutiny where, as here, the old product is facing loss of exclusivity; the new

product represents an insignificant change; and the manufacturer uses coercive tactics and/or misinformation about the generic to pressure a switch to the new product.

121. The 40mg product "did not demonstrate an enhanced efficacy" and, internally, Teva executives acknowledged that "every other day over once daily does not represent a significant improvement in convenience." In fact, senior Teva scientists were "strongly against" development of the 40mg product because it had "no scientific rationale/value." Teva's true motivation for bringing Copaxone 40mg to market, and engaging in the coercive campaign to switch patients from the 20mg product to the 40mg product, was to foreclose generic competition in the face of Teva's impending loss of market exclusivity for the 20mg product. Teva's product switch succeeded in suppressing generic competition because a generic that differs from the brand product in terms of dosage cannot be automatically substituted for the brand product.

1. The 40mg product was launched to create a "Barrier to generic entrance."

122. In late 2007, Sandoz filed its ANDA for generic Copaxone 20mg and in July 2008, Sandoz sent a Paragraph IV notice to Teva.

123. At that time, Teva had been conducting clinical trials comparing the efficacy of a new 40mg daily Copaxone to the existing 20mg Copaxone product. However, on July 7, 2008, Teva announced that its Phase III clinical trial had determined that there was no difference in efficacy between the 40mg product and the 20mg product. Almost immediately, Teva pivoted to examining whether it could stave off generic competition by instead changing the dosage regimen.

124. In internal emails with Teva's Senior Director of Innovative Projects regarding Copaxone Life Cycle Management, one executive asked, "Can we patent the frequency?" The author continued: "This is also a long-term plan, assuming Phase II and Phase III bringing us to 2016 – **still relevant?**" (emphasis added).

From: [redacted]
Sent: Tuesday, August 26, 2008 8:26 PM
To: [redacted]
Cc: [redacted]
Subject: Re: brief update from GIR meeting on GA LCM

Thanks for the update. A few points:

1. The limiting step with GA is the density of the solution. I assume that [redacted] has the information for the 60mg back from the days we have worked on the 80mg.
2. Please consider the ISR we saw in the rats with the 80mg (so we may not want to go to high).
3. In addition, we have currently a 5 fold safety ration based on monkeys only and excluding the ISRs - we should consider whether this should guide us when choosing the next dose.
4. What is the TPP - efficacy as 20mg?
5. Can we patent the frequency?
6. This is also a long term plan, assuming Phase II and Phase III bringing us to 2016 - still relevant?

[redacted]

125. In other words, would a new dosage regimen "still [be] relevant" if Teva could not get the new product to market until 2016, *i.e.,* after market entry of generic Copaxone 20mg? (As it turned out, the different dosing regimen *was* still relevant, because Teva was able to bring the three-times-weekly dosage to market in January 2014, in advance of generic Copaxone 20mg entering the market.)

126. In a 2008 presentation to the Board of Directors, Teva's executives presented new "Life Cycle Initiatives" that included Copaxone "40mg every other day." However, in a prior communication, a Teva executive had acknowledged that "every other day over once daily **does not represent a significant improvement** in convenience." (emphasis added).

127. By the end of 2008, Teva executives had nonetheless decided to pursue a study to support the 40mg every-other-day dosing regimen. The decision to pursue the study was made despite strong opposition from senior Teva scientists, who argued in a December 24, 2008 email that the study had "no scientific rationale/value." The email further noted that the Life Cycle Management team (the business team responsible for the Copaxone franchise) agreed with the scientists' decision, but believed the study had its "business value":

Dear both,

Please find below the presentation prepared for the discussion in the GA LCM meeting one month ago (the relevant study design can be found in slides 7-9- Option 2- Superiority study GA 32 mg thrice a week vs, placebo, and the appropriate FTE slide can be found in slide 14).

I would like to make it clear that the IR&D management, led by [redacted] are **strongly against the study** since it has no scientific rationale/ value. The IR&D decision was conveyed to the GA LCM team; however, the GA LCM members, though agree with IR&D decision, think that such a study has its business value.

I know from [redacted] that a GIR meeting is planned for 08-09 Jan 09, so I assume that a final decision will be taken then by [redacted]

Please contact me if you need any further clarifications.

All the best

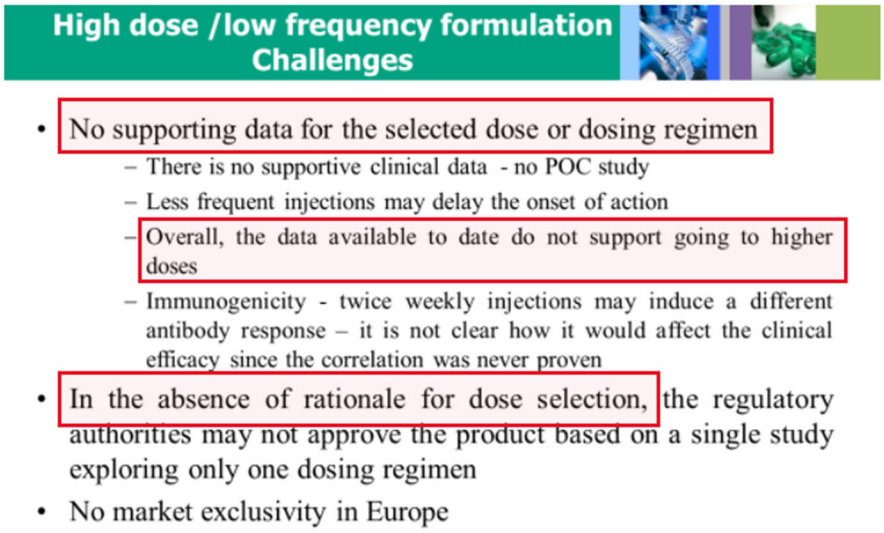
[redacted]

[attachment "GA infrequent injection- Optional scenarios- 19 Nov 08.ppt" deleted by Yifat Shorer/NTA/TEVA/IL]

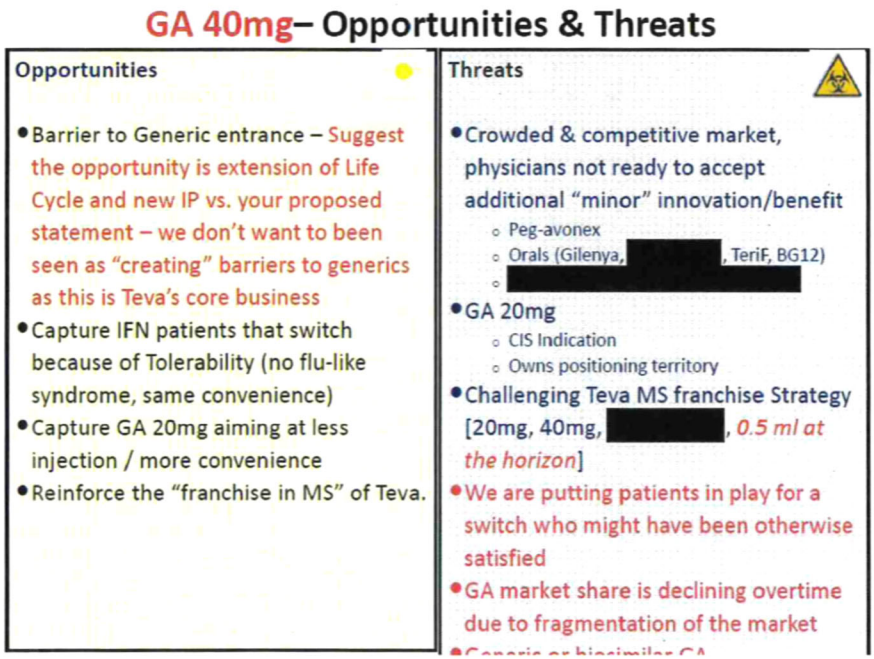
Yossi Gilgun-Sherki, Ph.D.
Global Clinical Leader
Clinical Development Section
Global Innovative R&D
Teva Pharmaceutical Industries, Ltd.
Netanya, Israel

Highly Confidential

128. Despite the lack of a "scientific rationale/value," and despite recognition that the less frequent dosage did "not represent a significant improvement in convenience," Teva continued to pursue the 40mg every-other-day dose. A June 2009 presentation to Teva's then-CEO Shlomo Yanai stressed that "The new formulation must be approved no later than 2014" (*i.e.,* in advance of generic entry) while simultaneous acknowledging that there was "[n]o supporting clinical data for the selected dose or dosing regimen" and that "[o]verall, the data available to date do not support going to higher doses." The presentation cautioned that the "absence of rationale for dose selection" could lead to regulatory denial:



129. However, Teva viewed the 40mg product as an "Opportunit[y]" to create a "Barrier to Generic entrance."



130. A senior Teva executive cautioned that this "Barrier to Generic entrance" language should be removed from the presentation, explaining, "we don't want to be seen as 'creating' barriers to generics as this is Teva's core business."

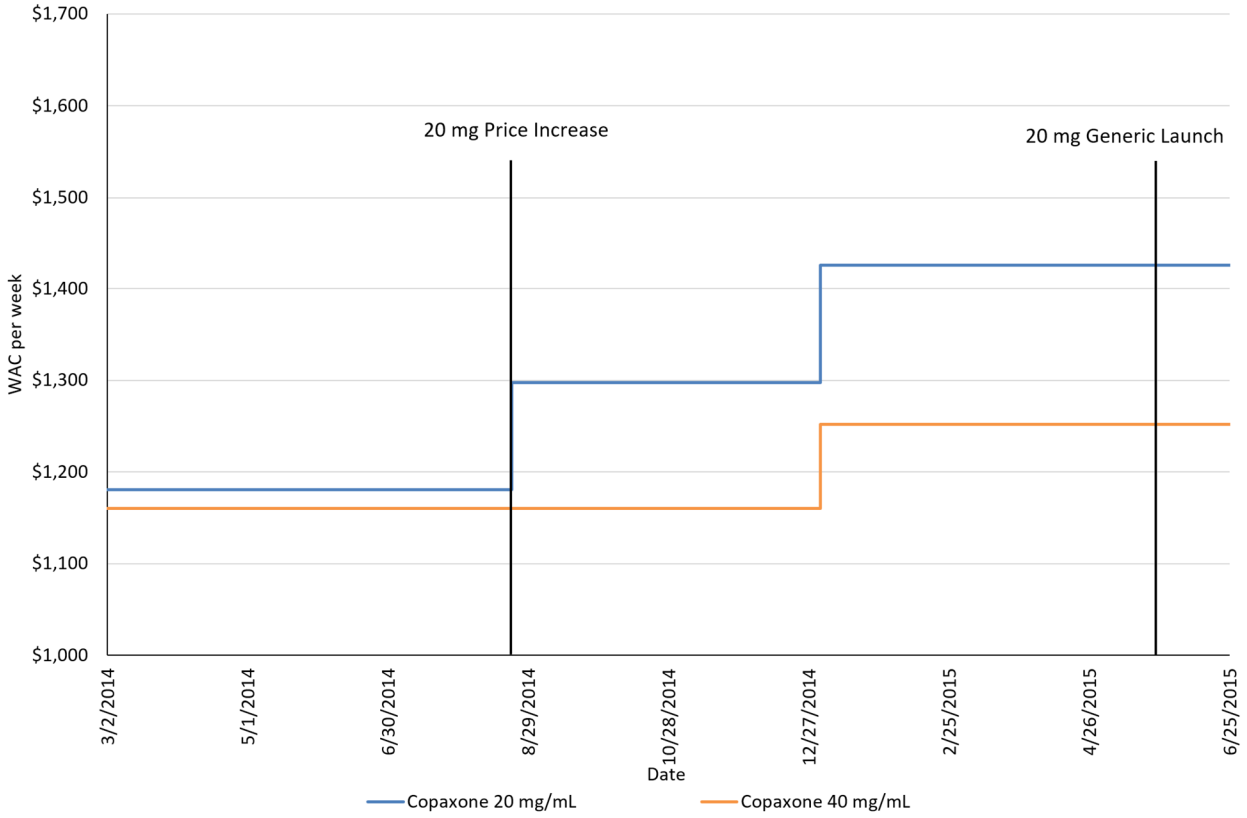
131. On January 28, 2014, Teva received FDA approval for its Copaxone 40mg product and launched the next day. Teva then began converting the market to the 40mg product, for which there was (at that time) no generic competition.

2. Teva leveraged its market power and used coercive tactics to switch the market to Copaxone 40mg to suppress generic competition.

132. Teva took several steps to ensure the "rapid transition of COPAXONE 20mg to 40mg prior to expected generics in mid-2014," including: (i) pricing the new 40mg lower than the 20mg product to pressure patients to switch; (ii) planning for the discontinuation of copay assistance for the 20mg product; (iii) causing PBMs to add the 40mg to their formularies by tying rebates; (iv) enlisting PBMs to aggressively lobby doctors to switch their patients to the new dosage; and (v) making Teva's sales forces' bonuses entirely contingent on sales of the 40mg.

133. Teva manipulated pricing in a few ways. First, at the time Teva launched the new 40mg dose, it priced the 40mg product *lower* than the 20mg product. If the 40mg product was, as Teva claimed, "a significant advancement," one would expect Teva to charge more (not less) for the superior product. Then, on August 22, 2014, Teva implemented a 9.8% price hike on the 20mg product, causing the older 20mg product to be priced significantly higher than the purportedly superior 40mg product.

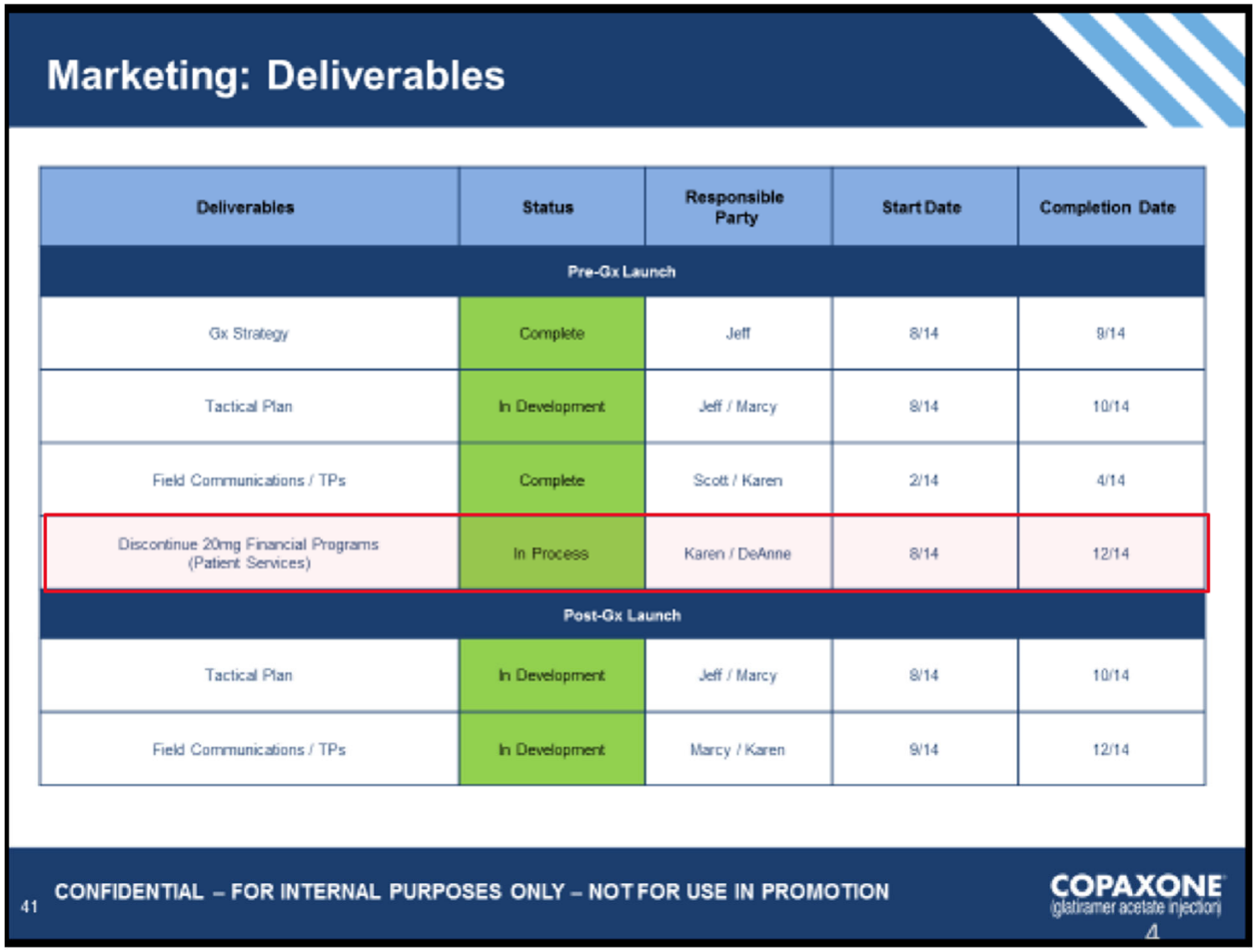
Figure 2: Copaxone Wholesale Acquisition Cost List Price per Week by Strength



Source: ProspectoRx WAC data.

134. A senior Teva executive made clear that the motivation behind these pricing decisions was to prevent generic competition, emphasizing in an internal email that "an important part of [Teva's] generic defense strategy is creating price separation between the 20mg and the 40mg."

135. Internal documents also show that Teva planned to "Discontinue 20mg Financial Programs (Patient Services)" to exert additional pressure on patients to switch to the new dosage.



Marketing: Deliverables

Deliverables	Status	Responsible Party	Start Date	Completion Date
Pre-Gx Launch				
Gx Strategy	Complete	Jeff	8/14	9/14
Tactical Plan	In Development	Jeff / Marcy	8/14	10/14
Field Communications / TPs	Complete	Scott / Karen	2/14	4/14
Discontinue 20mg Financial Programs (Patient Services)	In Process	Karen / DeAnne	8/14	12/14
Post-Gx Launch				
Tactical Plan	In Development	Jeff / Marcy	8/14	10/14
Field Communications / TPs	In Development	Marcy / Karen	9/14	12/14

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COPAXONE (glatiramer acetate injection)

136. In addition, Teva used PBMs to effectuate its product conversion scheme. As a first step, Teva forced PBMs to add the 40mg product to their formularies by conditioning the receipt of any Copaxone 20mg rebates on the PBM's agreement to add the 40mg product to the formulary. The tactic proved effective. Internal Teva emails show that after one PBM lost its 2015 rebates for failing to add the 40mg to its formulary, it got in line the following year and added it.

137. Teva also incentivized PBMs to lobby prescribers directly to switch patients from the 20mg to the 40mg. For example, under its "Copaxone conversion initiative," Humana agreed that it was "committed to converting current Copaxone 20mg patients over to Copaxone 40mg with their physician members" and further represented that, "Humana is contacting the prescribers via fax and phone to make them aware of which patients are still on Copaxone 20mg and encourage them to

switch these patients to Copaxone 40mg." The DOJ and courts have stated that "'conversion' requirements" such as this transform rebate payments into illegal kickbacks.

138. In addition, Teva used its sales force to press prescribers to switch their patients to the 40mg dose to block generic competition. For example, Teva's 2017 "Brand Plan" instructed its sales force to "[e]ncourage physicians to switch patients to [three times weekly] Copaxone 40mg if payers force to generic . . . for daily use." The Brand Plan further stated that sales representatives should push doctors to "[p]rescribe Copaxone DAW [Dispense as Written] for new and existing patients" and urge prescribers to "[e]ncourage their patients to accept only branded Copaxone."

139. To further incentivize its sales force to convert patients to 40mg Copaxone, Teva made their bonuses entirely dependent on 40mg sales. As one internal document put it: "The sales force is only paid on 40mg sales."

140. On June 18, 2015, Sandoz began selling generic Copaxone 20mg. However, because of Teva's coercive tactics, the vast majority of the market had been converted to the 40mg dosage, foreclosing competition from Sandoz's generic product. More specifically, by the end of 2015, Teva had converted approximately 77% of Copaxone patients to the 40mg product. In June 2016, approximately one year following the market entry of the generic 20mg product, Teva's General Manager of Neuroscience John Hassler circulated a presentation boasting that, "The strategy of switching patients to 40mg version of the medicine is continuing to be successful and reduce the impact of generic competition." By the end of 2016, Teva had succeeded in converting 84% of the market to the 40mg dosage.

141. Teva's product switch substantially foreclosed generic competition because it denied generic manufacturers a fair opportunity to compete using state substitution laws. It is widely recognized that generic substitution is the cost-efficient means for generic manufacturers to compete, which is due in part to the disconnect that exists between the person selecting the patient's

treatment and the person or entity who ultimately pays for that drug. As a result, the market forces that would ordinarily allow patients and other payors to consider price when making a product selection are absent. Moreover, a patient whose prescription had been converted to the 40mg product cannot simply ask that the pharmacist fill the prescription with generic 20mg; the two products are not A-rated equivalents and therefore the 20mg product may not be substituted for the 40mg.

142. Teva's coercive campaign to switch patients to the 40mg, which included, *inter alia,* price manipulation, PBMs pressuring doctors to switch patients, rebate tying, and conditioning the sales representatives' bonuses on 40mg sales only, effectively eliminated the free choice of consumers, forcing patients and Class members to purchase brand Copaxone 40mg despite the availability of more affordable generic Copaxone.

143. Moreover, Teva's product switch entailed moving its *existing* patients to a product that Teva priced *lower* than the old product. Teva's switch scheme therefore does not make economic sense, other than as a tool to impair generic competition. Teva's conduct also cannot be explained away as a simple effort to "win" consumers to a new product with discounts. Teva did not "win" consumers to the 40mg. It forcibly switched patients to the 40mg through a coercive campaign and then manipulated pricing to discourage patients and prescribers from reverting to the old product, which faced automatic generic substitution.

144. Experts estimate that Teva's coercive product switch cost the United States healthcare system between $4.3 billion and $6.5 billion in additional expenditures between 2015 and 2017.

B. Teva entered into exclusionary agreements to impede generic competition.

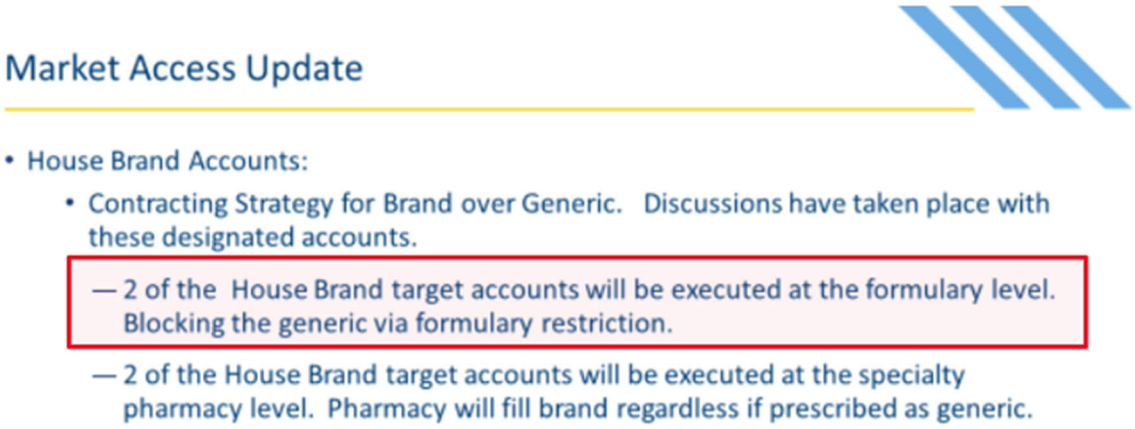
145. Although its product switch scheme was exceedingly effective at suppressing generic competition, Teva did not stop there. Internal Teva documents reveal that Teva entered into

exclusionary agreements with PBMs and specialty pharmacies that outright barred generic Copaxone from being dispensed. These exclusionary agreements severely restricted market access for generic Copaxone and substantially lessened competition, as Teva intended. Exclusionary agreements of this nature are particularly concerning where, as here, they are imposed by a monopolist. Teva entered into these exclusionary contracts in furtherance of its overarching scheme to extend its monopoly and suppress generic competition.

146. The Staff Report and certain documents cited therein suggest that one means Teva used to induce PBMs and specialty pharmacies to accept the exclusionary contracts was by paying rebates. However, Teva's rebates (or more precisely the impact of those rebates on pricing) was not the predominant mechanism of exclusion. Indeed, Plaintiffs allege they were denied the ability purchase *more affordable* generic Copaxone because of Teva's exclusionary scheme. Plaintiffs allege that, to prevent generic competition, Teva leveraged its monopoly power to block generic Copaxone from formularies and to ban generic Copaxone from being shipped. As a result of Teva's exclusionary conduct, generic manufacturers were denied the *opportunity* to compete, causing harm to competition and to Class members. Teva's exclusionary contracts were part of an overarching scheme to suppress generic competition.

1. Teva's exclusionary agreements with PBMs prevented patients' insurance plans from covering generic Copaxone.

147. In early 2017, Mylan was poised to enter the market with the second generic Copaxone 20mg product and the first generic Copaxone 40mg product. In response, Teva had begun to implement a two-part "Contracting Strategy for Brand over Generic." First, with respect to PBMs, Teva entered into exclusionary agreements that "Block[ed] the generic via formulary restriction."

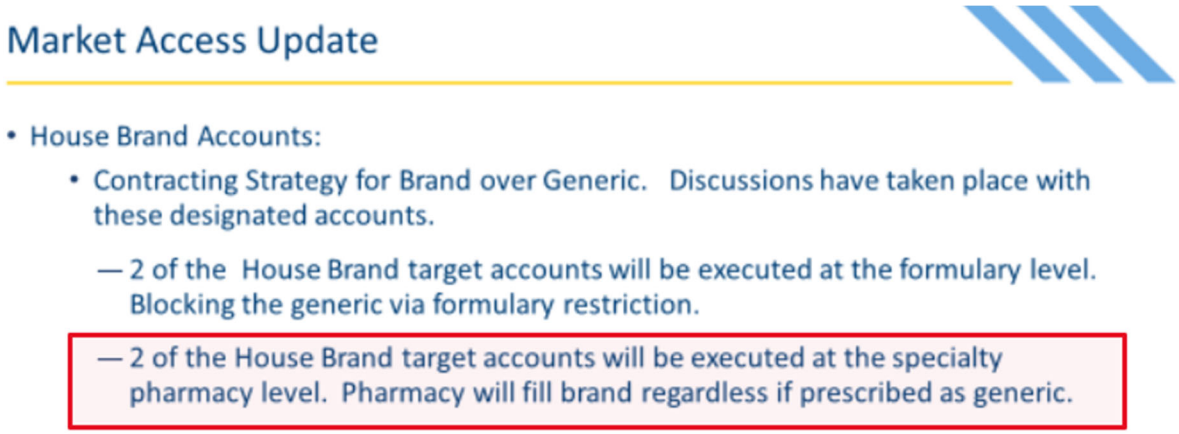


148. "Blocking" generic Copaxone "via formulary restriction" meant that generic Copaxone would be excluded from PBM formularies and therefore the cost of the generic drug would not be covered by health plans. As a result, patients receiving generic Copaxone would be forced to bear the full cost of generic Copaxone, while brand Copaxone continued to be listed on formularies and therefore covered by insurance. By cutting off generic Copaxone from formularies (and therefore from insurance coverage), Teva leverage its dominant market position to severely restrict patient access to generic Copaxone, substantially lessening competition.

149. Moreover, there is no cognizable, non-pretextual, procompetitive justification for Teva's exclusionary conduct that would outweigh its harmful effects. The exclusion of generic Copaxone from the PBM's formulary is at odds with the very purpose behind the formulary, *i.e.,* to provide high quality care using the most cost-effective options. A drug that has been approved by the FDA as an AP-rated generic is therapeutically equivalent to the brand drug. The only material difference between the generic and the brand is the substantially lower cost of the generic product.

2. Teva's exclusionary agreements with specialty pharmacies precluded the pharmacies from dispensing generic Copaxone.

150. Teva took an even more direct approach to excluding competition at the pharmacy level. In return for large payments, specialty pharmacies agreed that they would "fill brand regardless if prescribed as generic."



151. Teva's Executive Vice President for North America confirmed that the illegal agreement was indeed that blatant, stating in an internal email, "**[the specialty pharmacy] only ships brand Copaxone no matter how it is written or what the formulary states.**"

152. He further explained, "Because **[the PBM] is getting an additional rebate to fill all 'glatiramer' or Copaxone scripts with Copaxone … if a doctor orders generic glatiramer or the pharmacy benefit mandates it be filled as a generic, it will come in a plain box with Copaxone inside**."

On Jan 31, 2018, at 3:56 PM, Brendan O'Grady Highly Confidential wrote:

Because PBM is getting an additional rebate to fill all "glatiramer" or Copaxone scripts with Copaxone...if a doctor orders generic glatiramer or the pharmacy benefit mandates it be filled as a generic, it will come in a plain box with Copaxone inside. Win-win for all...

Best regards,

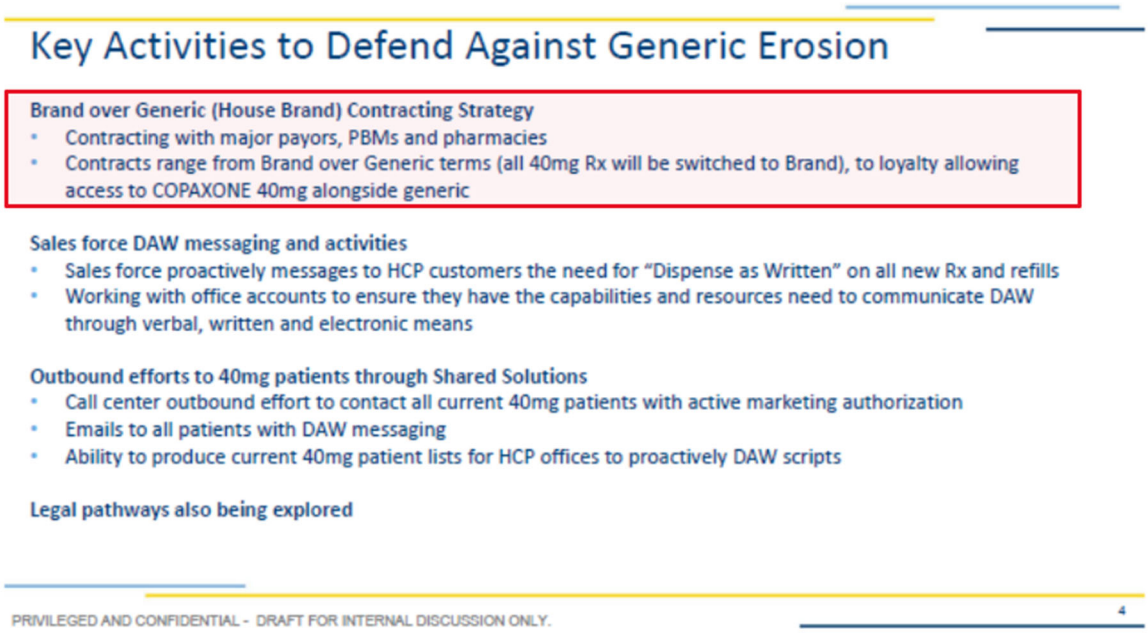
<image001.png> Brendan P. O'Grady EVP and Head of North America
Highly Confidential

<image002.png>

153. In other words, Teva was paying pharmacies to ignore doctors' orders and other substitution requirements and instead always ship brand Copaxone no matter what. In addition to violating the antitrust laws prohibiting exclusionary conduct, these payments to pharmacies violated the federal Anti-Kickback Statute. More specifically, the DOJ has made clear that where a drug manufacturer makes payments to a pharmacy to increase utilization of the manufacturers' drug, regardless of the label used, the payment will not fall within the safe harbor provision of the Anti-Kickback Statue, a federal statute that prohibits any entity from soliciting or receiving any remuneration "in return for purchasing . . . or recommending purchasing . . . any good . . . for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. §1320a-7b(b)(1).

154. The Teva executive concluded the email by stating that the arrangement was a "Win-win for all . . ." It was a "win" for Teva because it unlawfully extended Teva's monopoly and earned it billions of dollars in illegal profits; and it was a "win" for the PBM-owned specialty pharmacies that received the illegal kickbacks. However, it was a decided loss for generic competition, which was foreclosed by Teva's exclusionary conduct, and for payors who were constrained to purchasing brand Copaxone despite the availability of more affordable generic Copaxone.

155. There is no cognizable, procompetitive justification for Teva's agreements that pharmacies would ship only the brand product, even when the generic was prescribed (and in contravention of generic substitution laws). An internal October 2017 presentation to Teva's Board of Directors makes clear that Teva's "Brand over Generic (House Brand) Contracting Strategy" was undertaken not to compete, but to "Defend Against Generic Erosion":



156. Teva monitored and reported internally on the "success" of its scheme to suppress competition and frustrate generic uptake. For example, on October 26, 2017, Teva Neuroscience General Manager John Hassler reported to Teva's CEO Larry Downey that "Two weeks post generic approval, the team has had early success in achieving key Brand over Generic goals." Teva executives cautioned that the agreements were confidential and should not be shared even within the company.

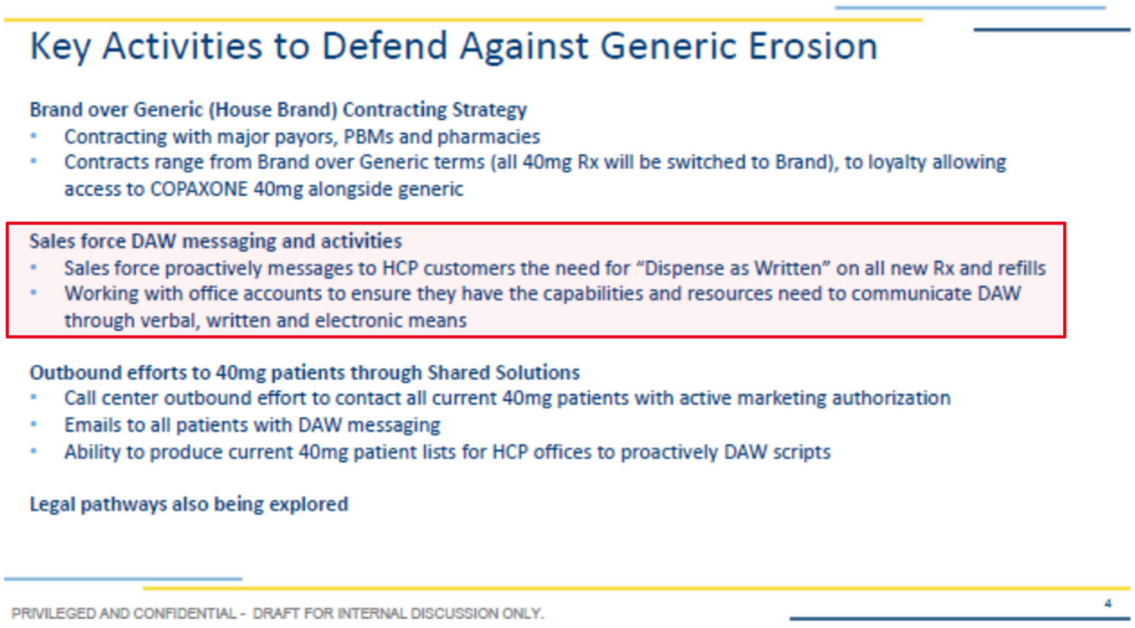
C. Teva engaged in an aggressive "Dispense as Written" campaign that depended in part on spreading misinformation about generic Copaxone.

157. Automatic generic substitution cannot occur if the prescriber writes "Dispense as Written" or "DAW" on the prescription. When this occurs, the pharmacist is prevented from

substituting a generic drug for the brand product, even though the generic drug has been approved by the FDA as therapeutically equivalent to the brand.

158. On October 3, 2017, Mylan received final FDA approval for its generic Copaxone 40mg and 20mg products and launched the following day. In response, Teva ramped up its "DAW" campaign, which included making untrue and misleading statements to doctors and patients regarding the efficacy, safety, and substitutability of generic Copaxone.

159. Teva's aggressive "Dispense as Written" campaign was deployed in part through Teva's sales force, which was tasked with (among other things) "proactively messaging [Health Care Provider ("HCP")] customers the need for 'Dispense as Written' on all new Rx and refills":



160. Because generic Copaxone is an FDA approved AP-rated generic, there would be no valid scientific basis for a claim that there was a "need" for health care providers to write "'Dispense as Written' on all new Rx and refills."

161. A lawsuit recently filed by drug manufacturer Mylan against Teva revealed that Teva "[d]rafted and propagated a playbook of false and misleading statements designed to dissuade health

care providers and MS patients from accepting generic [Copaxone] as part of a campaign to persuade doctors to prescribe, and patients to request, branded Copaxone 'dispense as written.'"

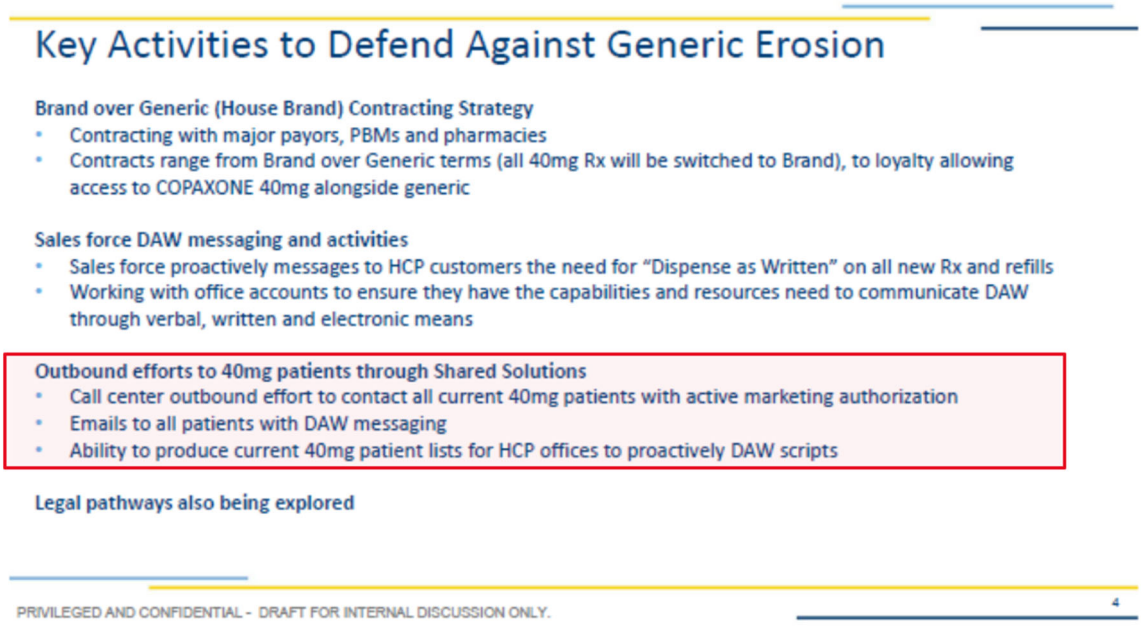
162. Teva persuaded doctors to write "Dispense as Written" on all Copaxone prescriptions in part by asserting, without any scientific basis, that generic Copaxone was only 80% to 85% as effective as branded Copaxone. Teva also wrongly asserted that Mylan did not offer injection training or nursing support to patients. Teva's misinformation campaign was pernicious, causing Mylan to go to unprecedented lengths to correct the misinformation, only to have providers refuse to speak to Mylan representatives about the issue:

> These false, misleading, and deceptive statements have caused health care providers and patients to avoid Mylan's generic GA product, impeded automatic substitution, and substantially reduced Mylan's sales. While Mylan, as a generic manufacturer, does not ordinarily market its generic drugs through sales representatives, it tried to correct Teva's misrepresentations by having company representatives communicate with health care providers. However, Mylan's efforts to revive its reputation were thwarted because a large number of providers already believed Teva's lies and refused to even talk to the Mylan representatives or argued with them using the arguments they heard from Teva.

163. Although they are sophisticated decisionmakers, doctors rely on drug manufacturers for information; and it is reasonable for a prescriber to expect that drug manufacturers will refrain from knowingly making representations that are objectively untrue. Here, Teva asserted, without any basis whatsoever, that the generic product was only 80% to 85% as effective as the brand product and that the generic product presented grave safety concerns (among other untrue statements). Assertions such as these, which appear to be fact-based but which are not, are difficult if not impossible to neutralize, as Mylan learned when it attempted to counter Teva's misinformation campaign.

164. Teva also used its patient services program, referred to as Shared Solutions, to bombard patients with its "Dispense as Written" campaign, using a call center to "contact all 40mg patients with active marketing authorization" and sending emails to "all patients with DAW messaging." According to Mylan, Teva's Shared Solutions personnel communicated misinformation

directly to MS patients about generic Copaxone, including wrongly asserting that generic Copaxone manufacturers did not offer training and nursing support and did not offer financial assistance. Teva also used Shared Solutions to "produce current 40mg patient lists" to provide to doctors' offices, so that they could "proactively DAW scripts."



Key Activities to Defend Against Generic Erosion

Brand over Generic (House Brand) Contracting Strategy
- Contracting with major payors, PBMs and pharmacies
- Contracts range from Brand over Generic terms (all 40mg Rx will be switched to Brand), to loyalty allowing access to COPAXONE 40mg alongside generic

Sales force DAW messaging and activities
- Sales force proactively messages to HCP customers the need for "Dispense as Written" on all new Rx and refills
- Working with office accounts to ensure they have the capabilities and resources need to communicate DAW through verbal, written and electronic means

Outbound efforts to 40mg patients through Shared Solutions
- Call center outbound effort to contact all current 40mg patients with active marketing authorization
- Emails to all patients with DAW messaging
- Ability to produce current 40mg patient lists for HCP offices to proactively DAW scripts

Legal pathways also being explored

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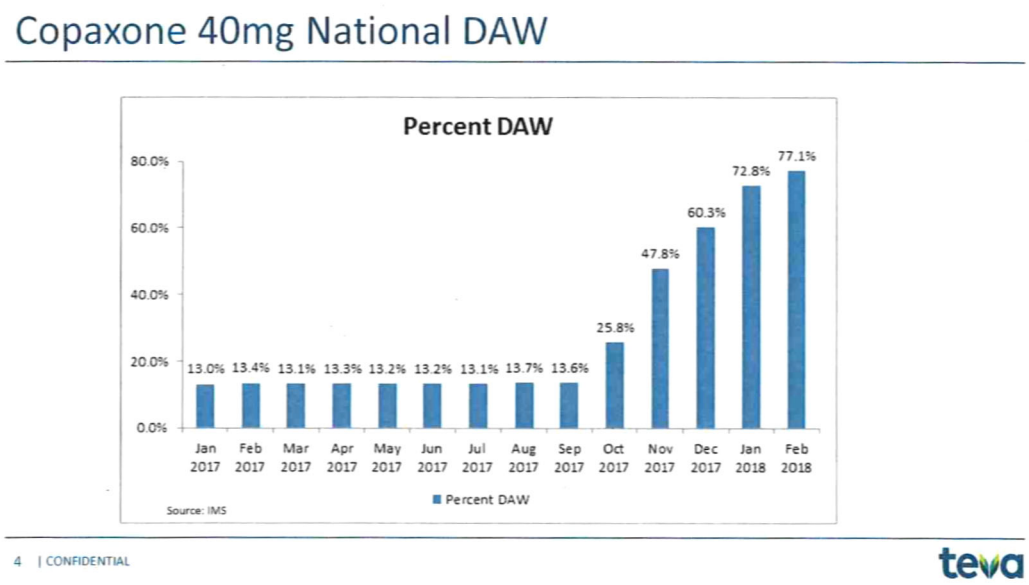
165. This is not a situtaion where Teva simply boasted about the superiority of its product in comparison to generic Copaxone. Rather, Teva made baseless, demonstrably untrue statements to patients, who necessarily rely on the information that drug manufacturers provide about their medications.

166. Rather than compete on the merits, Teva relied on defamation of generic Copaxone to advance its DAW campaign with the purpose of preventing generic competition. Teva's deceptive DAW campaign had its intended effect. According to internal reports, the rate at which "Dispense as Written" was noted on Copaxone 40mg prescriptions rocketed from approximately 13% to more than 77% in the four months following the launch of generic Copaxone 40mg."



167. This means that within months of the launch of generic Copaxone 40mg, Teva had locked up more than three-quarters of Copaxone 40mg prescriptions through its deceptive DAW campaign, such that generic Copaxone 40mg could not be substituted. In contrast, generic market share after one year is typically 90% or greater.

168. The Dispense as Written campaign was extremely lucrative for Teva. In August 2018, Teva's Executive Vice President for North America Brendan O'Grady remarked that the "DAW campaign combined with the legacy and house brand access strategy has paid great dividends." He continued: "I want to exceed $1.5 [billion] for the year on Copaxone. We did $900 [million] in [the first half of 2018] so we only need to do $50 [million+] in [the second half of 2018] to accomplish this goal." Teva succeeded in hitting this goal. In 2018, Teva's net revenue on Copaxone topped $1.6 billion, despite the availability of multiple generic Copaxone products, at least one of which had been on the market for more than three years.

169. The Dispense as Written campaign is ongoing and continues to harm generic competition.

D. Teva paid illegal kickbacks and made other payments to drive up brand Copaxone sales.

170. During the Class Period, Teva subsidized Copaxone patient out-of-pocket costs and offered other free services, which induced patients to purchase brand Copaxone instead of more cost-effective, therapeutically equivalent generic Copaxone.

171. Teva provided patient assistance through three primary channels. First, for Medicare patients, Teva provided cash donations to third party foundations to cover the patients' out-of-pocket cost for brand Copaxone. Second, for patients with commercial insurance, Teva offered the "Copaxone Co-Pay Solutions" program. Under this program, Teva covered the co-pay amount that patients would otherwise owe on their brand Copaxone purchases. Third, Teva offered patient services, such as free injection devices, to promote patient use of brand Copaxone and provide a forum for connecting patients with the financial aspects of Teva's patient assistance programs.

172. Teva characterized the kickbacks and other payments as, *e.g.,* "charitable cash contributions" and "donations" that justified Teva's price increases. In truth, Teva's payments were made with the purpose of driving up brand Copaxone sales, which increased Teva's revenues and suppressed generic competition.

173. Senior Teva management was aware of these payments. Indeed, some of the larger payments required approval from senior Teva executives, including Teva CEO Erez Vigodman:

Approval Authority Levels
$0.5M Sr. Director
$1M VP
$5M SVP (Larry Downey in the past)
$15M TEC members (Rob Koremans)
$25M CFO (Eyal Desheh)
>$25M CEO (Erez Vigodman)

1. Teva's donations violated the Anti-Kickback Statute.

174. The Anti-Kickback Statute, 42 U.S.C. § 13320a-7b(b), prohibits drug manufacturers from subsidizing the out-of-pocket costs of Medicare and Medicaid patients. Under the statute, a

drug manufacturer is prohibited from using charities to funnel money to patients with the intent of driving up the drug manufacturer's sales. Guidance provided by the Department of Health and Human Services explains that "pharmaceutical manufacturers can donate to *bona fide* independent charity [patient assistant programs]" where "appropriate safeguards exist." However, "the independent [patient assistance program] must not function as a conduit for payments by the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries' drug choices."

175. On August 19, 2020, the DOJ filed a lawsuit alleging that Teva paid illegal copay subsidies that violated the Anti-Kickback Statute. Beginning in 2006, Teva referred Medicare and Medicare-eligible patients who were taking Copaxone to Advance Care Scripts, Inc. ("ACS"), a specialty pharmacy, to assist the patients with obtaining Medicare Part D coverage and copay assistance. Concurrently, Teva was making cash donations to the Chronic Disease Fund ("CDF") (and later to The Assistance Fund ("TAF")), which operated a fund for MS patients intended to help cover the copay costs associated with various MS medications.

176. Teva coordinated the amount and timing of its donations to CDF and TAF to increase the likelihood that the payments would cover brand Copaxone copays only, thereby driving up brand Copaxone sales. Specifically, Teva worked closely with ACS (and later AssistRx) to calculate the exact amount needed to cover the Copaxone copayments for a specific number of patients. Teva then timed its donations to CDF and TAF to coincide with ACS's submission of a batch of patient applications to CDF and TAF. These two actions (*i.e.,* Teva transmitting payment and ACS submitting a batch of patient assistance applications) were also timed to occur when CDF's and TAF's MS funds had zero dollars available, thus maximizing the chance that Teva's donations would be funneled directly to Copaxone copays.

177. According to Edward Hensley, ACS's founder, Teva refused to provide funding to at least one charitable foundation due to its failure to limit funds to Copaxone copays only. Mr. Hensley attested that Denise Lynch, who served as Teva's Director of Customer Resources and later as Teva's Vice President of Patient Services, told Mr. Hensley that "she would not authorize donations to Patient Services Inc. ("PSI") because PSI had 'burned' her with respect to a prior donation," by which she meant that Teva's donation to PSI "had not been passed through to Copaxone patients, but rather had been used to cover the co-pays of patients who had been prescribed competitor MS drugs."

178. Mr. Hensley further attested that he "understood that Teva was purposefully utilizing ACS and structuring its donations to CDF in a manner that essentially ensured that such donations would benefit only Copaxone patients, and not patients who had been prescribed competitor MS medications."

179. Subsequently, when TAF took over the role of CDF, Mr. Henlsey "made sure that Ms. Lynch understood that Teva effectively would be able to use TAF as it had CDF: essentially, as a 'pass-through' donation vehicle to get Teva monies into the hands of Copaxone patients."

180. From 2006-2015, Teva paid more than $328 million in illegal kickbacks to drive up brand Copaxone sales. Information submitted to the House Committee indicates that Teva continued making these donations into 2018.

181. Teva knew that its donations to CDF and TAF increased Medicare claims for brand Copaxone and increased Teva's revenue. Internally, Teva characterized its patient assistance programs as an "investment" and tracked the specific "return on investment" ("ROI") associated with these programs, which was substantial. With respect to Teva's "Medicare Financial Assistance" program, the Staff Report estimated that the ROI was 200%.

182. Teva's illegal kickbacks drove up brand Copaxone sales and suppressed generic competition. Plaintiffs and Class members pay for and distribute brand and generic Copaxone, including most of the Copaxone and generic Copaxone products taken by Medicare, as well as Medicaid, patients. Plaintiffs and Class members were therefore harmed by having to purchase more expensive brand Copaxone instead of more cost effective generic Copaxone.

2. Teva's commercial copay assistance program induced patients to remain on brand Copaxone rather than switching to more affordable generic Copaxone.

183. Teva also had a copay assistance program for commercially insured patients, which similarly entailed Teva making payments to cover patient copays to drive brand Copaxone sales.

184. In 2007, CDF began administering Teva's Copaxone Private Copay Assistance Program.

From: Melissa Ayles [mailto:MAyles@cdfund.org]
Sent: Monday, November 05, 2007 10:14 AM
To: admin@cdfund.org
Subject: CD Fund now administering Copaxone Private Copay Assistance Program
Importance: High

Dear Participating Specialty Pharmacy,

Please be advised that effective November 1, 2007, Chronic Disease Fund began administering the Copaxone Private Copay Assistance Program. Should you identify privately insured patients in need of copay assistance, please refer them directly to Shared Solutions and identify yourself as making the referral. Shared Solutions will provide a daily feed of referrals to us with the pharmacy assignment included and we will, in turn, refer the patient back to you via the normal daily referral process. Please do not submit privately insured Copaxone patients to us via the daily referral process.

Please call me if you have any questions.

Best Regards,

Melissa Ayles
Senior Director, Partner Relations
Chronic Disease Fund, A Non-Profit Organization
10880 John W. Elliott Drive, Suite 400
Frisco, TX 75034

Direct: (214) 975-5180
Fax: (214) 975-1114
Cell: (972) 998-0837

185. As with its Medicare copay assistance program, Teva's ROI for its commercial copay assistance program was substantial. An internal report revealed that in 2015, Teva collected $148.2

million in net revenue from its $68.4 million expenditures on Teva's co-pay program for commercial patients.

186. Teva's Executive V.P. for North America touted internally that even if an insurer were to move brand Copaxone to the non-preferred tier of its formulary, the change "means little because we buy the patients [sic] copay down to zero anyway."

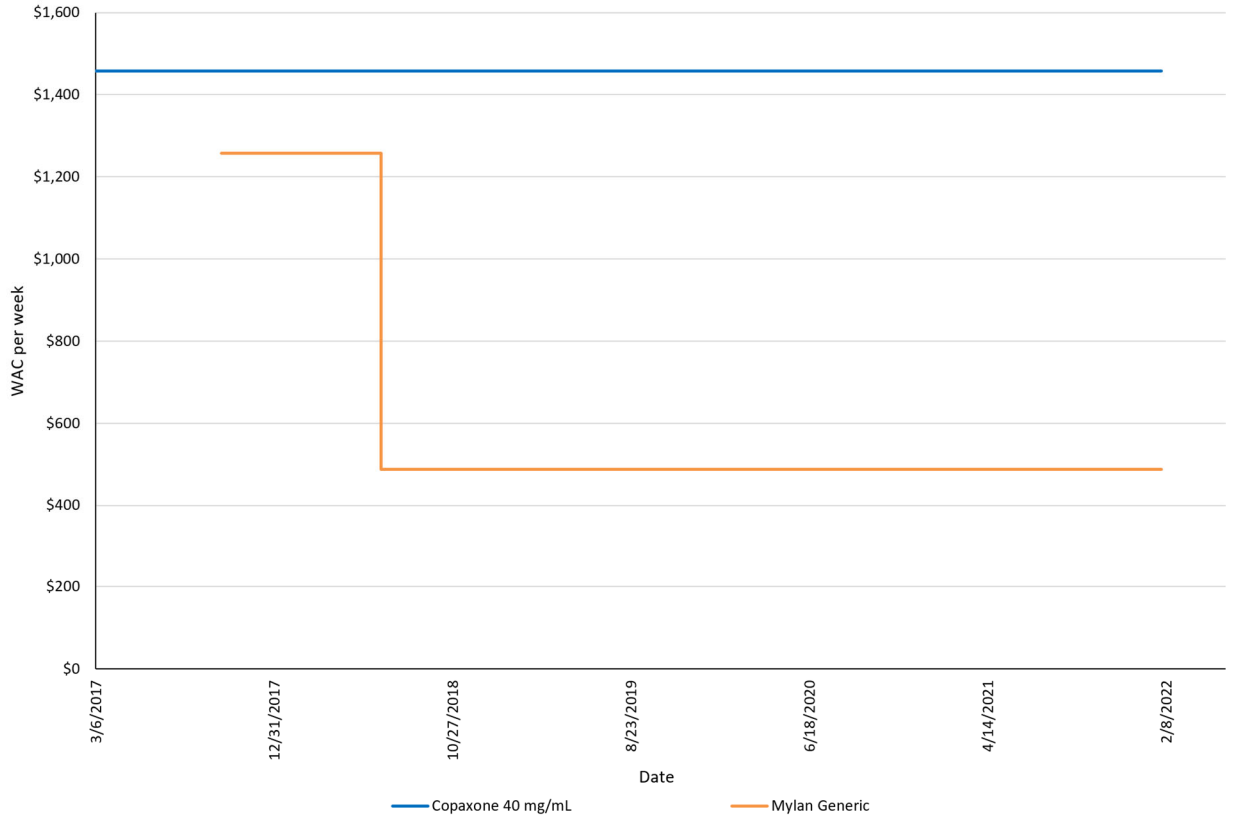
187. As a result of its commercial copay assistance program, Teva retained patients on brand Copaxone despite the availability of more cost effective generic Copaxone, causing Plaintiffs and Class members to purchase more brand Copaxone than they otherwise would have.

E. Teva's scheme has succeeded in suppressing generic competition.

188. The combined effect of Teva's multi-part monopolization scheme was to substantially foreclose generic competition, and unlawfully maintain Teva's dominant market share, for years. Although market share of the incumbent brand manufacturer typically falls to 10% or less within one year of generic entry, Teva continues to dominate the Copaxone market.

189. Teva was so effective at blocking generic Copaxone, even a 60% price cut by Mylan had only a muted impact on Teva's market share. Specifically, in July 2018, Mylan cut its price by more than half. (*See* Figure 3). Yet, as of June 2019, Teva still held more than 64% of the market.

Figure 3: Copaxone and Mylan Generic 40 mg Price per Week



Source: ProspectoRx WAC data.

190. In contrast, a typical generic entering a market will cause the corresponding brand market share to fall to 10% or less within a year.

191. Teva has openly boasted about the effectiveness of its scheme to suppress generic competition. For example, in November 2019, Teva touted to investors that, despite the years-long availability of more cost-effective generic Copaxone, Teva still held 63% of the market.

VII. CLASS ALLEGATIONS

192. Plaintiffs bring this action on behalf of themselves and, pursuant to Federal Rules of Civil Procedure 23(a) and 23(b)(3), as representatives of a class (the "Class") defined as:

> All persons or entities in the United States and its territories who purchased brand Copaxone from Defendants from June 18, 2015 until the anticompetitive effects of Defendants' conduct ceased (the "Class Period").

193. Excluded from the Class are Defendants and any of their officers, directors, management, employees, subsidiaries, and affiliates.

194. Also excluded from the Class are: (1) the government of the United States and all agencies thereof; and (2) all state or local governments and all agencies thereof.

195. Members of the Class are so numerous and geographically dispersed that joinder of all members is impracticable. Moreover, given the costs of complex antitrust litigation, it would be uneconomic for many plaintiffs to bring individual claims and join them together. The Class is readily identifiable from information and records in Defendants' possession.

196. Plaintiffs' claims are typical of those of the Class members. Plaintiffs and all Class members were damaged by the same wrongful conduct of the defendants—*i.e.*, because of Defendants' conduct, Class members were forced to purchase branded Copaxone, despite the availability of more cost-effective generics.

197. Plaintiffs will fairly and adequately protect and represent the Class's interests. Plaintiffs' interests are coincident with, and not antagonistic to, those of the other Class members.

198. Counsel representing Plaintiffs are experienced in the prosecution of class action antitrust litigation, and have extensive experience with class action antitrust litigation involving pharmaceutical products.

199. Questions of law and fact common to the Class members predominate over questions that may affect only individual Class members because Defendants have acted on grounds generally applicable to the entire Class. This conduct renders overcharge damages with respect to the Class as a whole appropriate. Such generally applicable misconduct is inherent to the Defendants' wrongful actions.

200. Questions of law and fact common to the Class include:

a. Whether Teva engaged in an unlawful scheme to suppress competition;

b. Whether Teva unlawfully maintained monopoly power through all or part of its overall generic suppression scheme;

c. Whether there exist any legitimate, non-pretextual, procompetitive justifications for some or all of Teva's conduct;

d. To the extent any such procompetitive benefits exist, whether there were less restrictive means of achieving them;

e. Whether direct proof of Teva's monopoly power is available and, if so, whether it is sufficient to prove Teva's monopoly power without need to define the relevant market;

f. Whether Teva's scheme, in whole or in part, has substantially affected interstate commerce;

g. Whether Teva's conduct harmed competition;

h. Whether Teva possessed the ability to suppress generic competition for Copaxone;

i. Whether Teva's unlawful conduct was a substantial contributing factor in causing some amount of suppression of generic competition; and

j. The quantum of overcharges paid by the Class in the aggregate.

201. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would require. The benefits of proceeding through the class mechanism—including providing injured persons or entities with a method for obtaining redress on claims that they could not practicably pursue on an individual basis—substantially outweigh potential difficulties in management of this class action.

202. Teva's anticompetitive conduct has imposed and will continue to impose (unless Plaintiffs obtain equitable relief) a common antitrust injury on Plaintiffs and all Class members. Teva's anticompetitive conduct and its relationships with the Class members have been substantially uniform. Teva has acted and refused to act on grounds that apply to the class generally, and injunctive and other equitable relief is appropriate respecting the class as a whole.

203. Plaintiffs know of no special difficulty in litigating this action that would preclude its maintenance as a class action.

VIII. MARKET POWER AND RELEVANT MARKET

204. At all relevant times, Teva had substantial market power in the market for Copaxone and its generic equivalents. Teva had the power to maintain Copaxone prices at supracompetitive levels without losing sufficient sales to other products, except for AP-rated generic versions of Copaxone, to make the supracompetitive prices unprofitable.

205. A significant, non-transitory increase in the price of brand Copaxone, above the competitive level, did not cause a significant loss of sales to any product other than AP-rated versions of Copaxone. At competitive prices, brand Copaxone does not exhibit significant, positive cross-elasticity of demand with any product or treatment for RRMS other than AP-rated generic versions of Copaxone.

206. Direct evidence of Teva's market power includes the following: (a) from 2013 to 2018, the per-unit manufacturing cost for Copaxone was less than 3% of the net price of the drug, *i.e.,* the price after adjusting for rebates and discounts; (b) when generic Copaxone eventually entered the market, it took a portion of brand Copaxone's unit sales; (c) Teva never lost Copaxone sales in response to pricing of other brand or generic drugs, except for AP-rated generic Copaxone; (d) Teva never lowered the price of Copaxone to the competitive level in response to pricing of other brand or generic drugs; and (e) from 2006 to 2015, prior to generic entry, Defendants profitably raised the price of Copaxone 20mg by approximately 350%.

207. Teva's power to profitably raise these prices above the competitive level results in substantial part from a significant imperfection in the United States marketplace for prescription pharmaceuticals. Brand drug manufacturers can exploit this imperfection to obtain or maintain market power.

208. Markets function best when the person responsible for paying for a product is also the person who chooses which product to purchase. When the same person has both the product choice and the payment obligation, the product's price plays an appropriate role in the person's choice and, consequently, manufacturers have an appropriate incentive to reduce their prices to the competitive level.

209. In the pharmaceutical marketplace, there is a disconnect between product selection and payment. State laws prohibit pharmacists from dispensing many pharmaceutical products, including Copaxone, to patients without a prescription. Patients must obtain prescriptions from their physicians. However, a patient's physician has no role in the purchase of the prescription medication.

210. The patient's doctor chooses which product the patient will buy, while the patient (and in most cases his or her insurer) must pay for it. Brand manufacturers, including Teva, exploit this disconnect by employing large sales forces that visit doctors' offices and persuade them to prescribe the brand manufacturers' products. These sales representatives do not advise doctors on the cost of their branded products. Studies show that doctors are typically unaware of the relative costs of brand pharmaceuticals and, even when they are aware, are largely insensitive to price differences because they do not pay for the products. The result is a marketplace where price plays a comparatively unimportant role in product selection.

211. The relative unimportance of price in the pharmaceutical marketplace reduces what economists call the price elasticity of demand—the extent to which unit sales go down when price goes up. This reduced price elasticity enables brand manufacturers to raise prices substantially above marginal cost without losing enough sales to make the price increase unprofitable. The ability to profitably raise prices substantially above marginal costs is what economists and antitrust courts refer to as market power.

212. The result of these pharmaceutical market imperfections and marketing practices is that brand manufacturers gain and maintain market power with respect to many brand prescription pharmaceuticals, including Copaxone.

213. During the relevant time, Teva had monopoly power in the market for Copaxone and AP-rated generic substitutes because it had the power to exclude competition and/or raise or maintain the price of Copaxone to supracompetitive levels without losing enough sales to make these prices unprofitable.

214. Brand Copaxone is therapeutically differentiated from all RRMS products other than AP-rated generic versions of Copaxone. The availability of other RRMS disease-modifying treatments has not constrained Teva. Teva has continually increased the prices for Copaxone over the years, even when new RRMS injectable disease-modifying therapies were approved by the FDA.

215. To the extent that Plaintiffs are required to prove market power through circumstantial evidence by first defining a relevant product market, Plaintiffs allege that the relevant antitrust market is the market for Copaxone and its AP-rated generic equivalents.

216. At all relevant times, Teva was protected by high barriers to entry due to patent protection, the high cost of entry and expansion, expenditures in marketing and physician detailing, and state statutes that require prescriptions for the purchase of the products at issue and restrict substitution of those products at the pharmacy counter. The products in these markets require significant investments of time and money to design, develop, and distribute. In addition, the markets require government approvals to enter and/or the drugs at issue may be covered by patents or other forms of intellectual property. Teva's unlawful conduct further restricted entry. Thus, during the relevant time, existing and potential market entrants could not enter and/or expand output quickly in response to Teva's higher prices or reduced output.

217. The relevant geographic market is the United States and its territories. Teva's market share in the relevant market was 100% until Sandoz's generic entry in June 2015. Even after generic entry, Teva maintain a majority of the glatiramer acetate market for a significant period of time.

IX. EFFECT ON INTERSTATE COMMERCE

218. During the relevant time period, Teva manufactured, sold, and shipped Copaxone across state lines in an uninterrupted flow of interstate commerce.

219. During the relevant time period, Plaintiffs and Class members purchased substantial amounts of Copaxone directly from Teva. As a result of Teva's illegal conduct, Plaintiffs and Class members were compelled to purchase brand Copaxone, despite the availability of more cost-effective generic alternatives.

220. During the relevant time period, Teva used various devices to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign wire commerce. Teva engaged in illegal activities, as charged in herein, within the flow of—and substantially affecting—interstate commerce, including in this district.

X. TEVA CONCEALED ITS UNLAWFUL CONDUCT

221. A cause of action accrued for Plaintiffs each time a brand Copaxone product was sold to Plaintiffs, who would have purchased the more affordable generic version instead, but for Teva's anticompetitive scheme. Each sale of brand Copaxone constituted an overt act in furtherance of Teva's continuing anticompetitive scheme. Other overt acts in furtherance of Teva's continuing misconduct include, but are not limited to: implementing and enforcing exclusionary agreements with PBMs to bar generic Copaxone from formularies; obtaining and enforcing agreements with specialty pharmacies so that the branded product is always shipped, even when generic is prescribed; spreading misinformation about generic Copaxone to convince prescribers to write DAW on all Copaxone prescriptions; and paying illegal kickbacks and otherwise using Teva's patient assistance

programs to drive up brand sales. As a result, Plaintiffs are entitled to recover damages on its brand Copaxone purchases within four years of the filing of this lawsuit.

222. Due to the fraudulent concealment of Teva's unlawful conduct, Plaintiffs and Class members are entitled to recover damages extending back beyond four years prior to the filing of this complaint. Plaintiffs and Class members had no knowledge of Teva's unlawful scheme and could not have discovered the scheme through the exercise of reasonable diligence more than four years before the filing of this complaint.

223. Plaintiffs and Class members could not have known that Teva was entering into exclusionary agreements with PBMs and specialty pharmacies to bar generic Copaxone until the House Committee published its report on September 30, 2020. Teva took steps to keep these anticompetitive agreements secret. This included senior Teva executives warning subordinates that the exclusionary agreements with PBMs and specialty pharmacies should not be shared even internally with other Teva employees due to their "confidential nature." Moreover, internal communications discussing the exclusionary contracts were prominently stamped with the admonition: "DO NOT COPY. DO NOT DISTRIBUTE."

224. Plaintiffs and Class members also could not have known, prior to publication of the Staff Report, that Teva's pursuit of the new 40mg product was motivated by a desire to create a "Barrier to Generic entrance" and that the effort was opposed by senior Teva scientists. Nor could Plaintiffs have known that Teva was coercing PBMs into adding Copaxone 40mg to their formularies through rebate tying and that Teva was enlisting PBMs to aggressively lobby doctors to convert their patients to the new 40mg product.

225. Teva also gave pretextual justifications for its Copaxone pricing, which in truth was driven by a desire to force patients to switch from the 20mg to the 40mg product. For example, a set of October 2016 talking points "Intended for use by Copaxone Communications, [Investor

Relations] and Teva Leadership" instructed that, if asked about why Copaxone 40mg was priced lower than the 20mg product, the speaker was to respond that "COPAXONE 40m/mL offers a strong value proposition when compared to [Sandoz's generic Copaxone 20mg product] Glatopa." Teva also claimed that its Copaxone pricing was due, not to its illegal monopoly, but to its ongoing R&D efforts. In truth, as the House Committee reported, "Teva was unable to identify any R&D expenditures related to Copaxone after 2015." Through these and other statements, Teva concealed the truth that its Copaxone pricing was the result of, and in furtherance of, its illegal scheme to suppress generic competition.

226. Similarly, Plaintiffs and Class members could not have known about Teva's "Dispense as Written" campaign until the issuance of the Staff Report. And only subsequently, when Mylan filed its lawsuit against Teva on June 29, 2021, did it come to light that Teva's "Dispense as Written" campaign was fueled by misrepresentations regarding generic Copaxone, including untrue statements about the efficacy of the generic products.

227. One aspect of Teva's overarching monopolization scheme, Teva's payment of illegal kickbacks to drive up brand sales, became public prior to the publication of the September 30, 2020 Staff Report. Specifically, on November 20, 2019, the DOJ announced that it had entered into a settlement agreement with TAF regarding its role in the illegal kickback scheme and, on August 18, 2020, the DOJ filed a lawsuit against Teva arising out of this misconduct. Teva and its co-conspirators – CDF, TAF, ACS, and AssistRx – took steps to conceal that Teva's donations were not legitimate charitable donations to aid multiple sclerosis patients, but in fact were illegal kickbacks calculated, coordinated, and timed to cover Copaxone copays only.

228. It was not until the House Committee issued its explosive report a few weeks later, on September 30, 2020, that Teva's exclusionary contracts and other key aspects of Teva's monopolization scheme began to come to light. Notably, the Staff Report was based on the House

Committee's review of over 300,000 pages of internal, nonpublic documents and communications produced by Teva to the Committee in response to a formal request. Similarly, the Mylan complaint filed in June 2021 set forth information that could not have been known by Plaintiffs prior to the filing of that action.

229. Teva's illegal monopolization scheme was also inherently self-concealing because, as Defendants knew, its disclosure would have exposed it to civil liability and governmental enforcement actions, as in fact occurred when the scheme came to light. *See e.g., Mylan Pharmaceuticals Inc. v. Teva Pharmaceuticals Industries Ltd, et al.,* case no. 21-cv-13087 (D.N.J.) (complaint filed June 29, 2021); *see also Humana Inc. v. Teva Pharmaceuticals USA, Inc.,* case no. 21-cv-00072 (M.D.Fla.) (complaint January 8, 2021).

230. Teva's business practices are subject to the antitrust laws, and so it was reasonable for Plaintiffs and Class members to presume that Teva was operating in a competitive market. A reasonable person under the circumstances would not have had occasion to suspect that Teva was engaged in an overarching monopolization scheme to suppress generic competition until September 30, 2020, when the Staff Report was published. One aspect of this scheme, the payment of illegal kickbacks, could have become known to the public slightly earlier, when the DOJ announced its settlement with TAF on November 20, 2019 and subsequently filed suit against Teva for its role in the illegal kickback scheme on August 18, 2020.

231. Because Teva's monopolization scheme is self-concealing and was affirmatively concealed by Teva, Plaintiffs and Class members had no knowledge of the scheme more than four years before the filing of this complaint. As a result of Teva's fraudulent concealment, all applicable statutes of limitations affecting Plaintiffs' and Class members' claims have been tolled.

XI. CLAIMS FOR RELIEF

COUNT ONE
VIOLATION OF 15 U.S.C. § 2

(Exclusive Dealing)

232. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

233. Defendants violated 15 U.S.C. § 2 by monopolizing the market for Copaxone in the United States.

234. At all relevant times, Teva possessed substantial market power (*i.e.,* monopoly power) with respect to Copaxone and its AP-rated equivalents. Teva possessed the power to control prices in the relevant market, to prevent prices from falling in the relevant market, to exclude competitors from the relevant market and to suppress generic competition.

235. That market power is coupled with strong regulatory and contractual barriers to entry into the market.

236. As alleged extensively above, Teva willfully maintained monopoly power by using restrictive or exclusionary conduct, rather than using greater business acumen. This conduct injured Plaintiffs and the Class.

237. Teva's conscious objective was to further its dominance through exclusionary conduct.

238. As stated more fully above, Teva knowingly, willfully, and wrongfully maintained monopoly power and harmed competition by:

i. Entering into exclusionary contracts with PBMs and specialty pharmacies to exclude generic Copaxone from formularies and bar specialty pharmacies from dispensing generic Copaxone.

239. Teva's anticompetitive conduct is exclusionary conduct—the purpose and effect of which is to willfully maintain monopoly power, which harms purchasers, the competitive process, and consumers, in violation of § 2 of the Sherman Act.

240. To the extent that Teva is permitted to assert one, there is and was no cognizable, non-pretextual, procompetitive justification for its exclusionary conduct that outweighs its harmful effects. Even if there were some conceivable justification that Teva were permitted to assert, its conduct is and was broader than necessary to achieve such a purpose.

241. Plaintiffs and the Class have been injured and will continue to be injured —unless they obtain equitable relief—in their business and property as a result of Teva's continuing monopolization in violation of § 2 of the Sherman Act.

COUNT TWO
VIOLATION OF 15 U.S.C. § 2

(Overarching Monopolization Scheme)

242. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

243. Teva violated 15 U.S.C. § 2 by monopolizing the market for Copaxone in the United States.

244. At all relevant times, Teva possessed substantial market power (*i.e.,* monopoly power) with respect to Copaxone and its AP-rated equivalents. Teva possessed the power to control prices in the relevant market, to prevent prices from falling in the relevant market, to exclude competitors from the relevant market, and to suppress generic competition.

245. That market power is coupled with strong regulatory and contractual barriers to entry into the market.

246. As alleged above, Teva willfully maintained monopoly power by using restrictive or exclusionary conduct, rather than using greater business acumen. This conduct injured Plaintiffs and the Class.

247. Teva's conscious objective was to further its dominance through exclusionary conduct.

248. As stated more fully above, Teva knowingly, willfully, and wrongfully maintained monopoly power and harmed competition through an anticompetitive scheme that included:

ii. Entering into exclusionary contracts with PBMs and specialty pharmacies to exclude generic Copaxone from formularies and bar specialty pharmacies from dispensing generic Copaxone;

iii. Implementing a coercive product switch to thwart generic competition;

iv. Engaging in an aggressive Dispense as Written campaign that relied in part on misinformation about generic Copaxone, including untrue statements that the FDA-approved generic product was less effective; and/or

v. Paying illegal kickbacks and manipulating commercial copays to suppress generic competition.

249. Teva's anticompetitive conduct is exclusionary conduct—the purpose and effect of which is to willfully maintain monopoly power, which harms purchasers, the competitive process, and consumers, in violation of § 2 of the Sherman Act.

250. To the extent that Teva is permitted to assert one, there is and was no cognizable, non-pretextual, procompetitive justification for its exclusionary conduct that outweighs its harmful effects. Even if there were some conceivable justification that Teva was permitted to assert, its conduct is and was broader than necessary to achieve such a purpose.

251. Plaintiffs and the Class have been injured and will continue to be injured —unless they obtain equitable relief—in their business and property as a result of Teva's continuing monopolization in violation of § 2 of the Sherman Act.

COUNT THREE
VIOLATION OF THE RICO ACT, 18 U.S.C. § 1962(c)

(Medicare Kickbacks)

252. Plaintiffs hereby repeat and incorporate by reference each preceding and succeeding paragraph as though fully set forth herein.

253. Defendants and their co-conspirators are "person[s]" within the meaning of 18 U.S.C. § 1961(3), who conducted the affairs of an enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c).

254. Defendants and their co-conspirators designed and coordinated illegal kickbacks (the "Copaxone Enterprise") to increase brand Copaxone sales, including through a conspiracy to defraud payors such as Plaintiffs and Class members. The Copaxone Enterprise consisted of illicit patient copay subsidies through sham charitable funds at least from June 2015 through 2018.

255. The Copaxone Enterprise is an association-in-fact within the meaning of 18 U.S.C. § 1961(4), consisting of Teva, ACS, AssistRx, CDF, and TAF. The Copaxone Enterprise was an ongoing organization that functioned as a continuing unit. The Copaxone Enterprise was created and/or used as a tool to effectuate a pattern of racketeering activity. Teva, ACS, AssistRx, CDF, and TAF are each "persons" distinct from the Copaxone Enterprise.

256. Teva established the Copaxone Enterprise to fraudulently increase its sales of brand Copaxone. With the aid of ACS and later AssistRx, Teva made donations to CDF and TAF that were targeted specifically to cover Copaxone copays only. Defendants knew that these payments violated the Anti-Kickback Statute.

257. Every Defendant and each of the co-conspirators knowingly participated in the Copaxone Enterprise and carried out their respective roles in furtherance of the Copaxone Enterprise. ACS and/or AssistRx coordinated the receipt of information from CDF and/or TAF so that Teva could calculate the donations needed to cover Copaxone copays only. Teva would then

coordinate the timing of its donations to coincide with when ACS and later AssistRx submitted patient application batches to the charitable foundations, thereby increasing the likelihood that the donations would cover Copaxone copays only. The donations were further timed to occur when the foundations' MS funds were at zero, maximizing the control that Teva had over how the funds would be spent. CDF and TAF understood, agreed to, and did use Teva's donations to cover the copay for brand Copaxone only, rather than other MS drugs.

258. Teva has asserted control over the Copaxone Enterprise by designing, organizing, and funding the sham charitable donations to CDF and TAF, which in truth were intended for use only in connection with brand Copaxone copays.

259. During the Class Period, the Copaxone Enterprise's unlawful conduct and wrongful practices were carried out by an array of employees, working across state boundaries, including from corporate headquarters in North Wales, PA and subsequently Parsippany-Troy Hills, NJ (Teva); Dallas, TX (CDF); and Orlando, FL (TAF). Activities affecting interstate commerce included: interstate wire transmissions of donations from Teva to CDF and TAF; the transmission of invoices charging Plaintiffs and Class members for fraudulent sales of brand Copaxone; the receipt of payments by Teva from Plaintiffs and members of the Classes for their brand Copaxone purchases; and the transmission of untrue or incomplete statements intended to mislead health care purchasers regarding the existence, amount, and purpose of Teva's Copaxone patient assistance payments.

260. Teva employed the U.S. Mail and interstate wires to carry out the Copaxone Enterprise, including the following:

a. Teva made sixty-six (66) donations via wire transfer to CDF and/or TAF beginning on December 31, 2006 and continuing through December 28, 2015 totaling $328,632,000. This included donations transmitted on September 3, 2015 (totaling $15,000), September 9, 2015 (totaling $250,000), and December 28, 2015 (totaling

$30,000,000), all of which were paid to TAF. Internal Teva documents indicate that wire transfers were effectuated at Teva's former headquarters in North Wales, PA and the funds intended for TAF were transmitted to a bank in Orlando, Florida. Teva continued to make these donations through at least 2018. According to Teva's counsel, it paid more than $23 million in donations in 2018 alone.

b. Under the terms of the Service Agreement between Teva and ACS, if Teva or ACS were required "to give any notice, demand or request with respect to this Agreement" the communication would only be effective if it was "in writing and delivered by personal service, facsimile transmission . . ., courier service. . . or mailed, certified mail . . . addressed to" (respectively) Orlando, Florida or Kansas City, MO.

c. Under the terms of the Donation Agreement between Teva and CDF, "[a]ll notices or other communications required or permitted hereunder will be in writing and will be delivered personally, by commercial overnight delivery service, by facsimile or sent by certified, registered or express air mail" to Denise Lynch of Teva Neuroscience, Inc. in Kansas City, MO or to Michael Banigan, President of CDF, in Frisco, TX, as applicable.

d. Defendants and their co-conspirators relied extensively on email to effectuate the illegal Copaxone Enterprise, including emails related to *inter alia*: (a) calculating the amount needed to cover Copaxone copays specifically; (b) coordinating the timing of Teva's donations to coincide with the submission by ACS (and later AssistRx) of patient application batches; and (c) obtaining the necessary authorizations within Teva to make the donations.

e. Teva used the U.S. mail and/or wires to transmit invoices containing charges for fraudulently obtained brand Copaxone purchases. Given the number of brand Copaxone sales during the Class Period, it is believed that hundreds of such invoices were transmitted.

f. Teva used the U.S. mail and/or wires to receive payments from Plaintiffs and the Class for purchases of brand Copaxone that constituted the wrongful proceeds of the racketeering activity in which Defendants and the co-conspirators engaged.

261. Teva has conducted, and Defendants and their co-conspirators participated in, the affairs of the Copaxone Enterprise through a pattern of racketeering activity that includes acts indictable under 18 U.S.C. §§ 1341 (mail fraud), 1343 (wire fraud), and 1952 (use of interstate facilities to conduct unlawful activity).

262. The effect of Defendants' and their co-conspirators' racketeering activity was to induce sales of brand Copaxone that otherwise would not have been made in the absence of the illegal conduct. Plaintiffs suffered injuries when they purchased brand Copaxone, despite the availability of more cost-effective generic Copaxone. Plaintiffs' injuries were directly and proximately caused by Defendants' and their co-conspirators' racketeering activities.

263. By virtue of these violations of 18 U.S.C. § 1962(c), Defendants are jointly and severally liable to Plaintiffs and the Class for three times the amount of the damages suffered, plus the cost of this suit, including reasonable attorneys' fees.

XII. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs, on behalf of themselves and the proposed Class, respectfully demand that this Court:

[A] Determine that this action may be maintained as a class action pursuant to Rules 23(a), (b)(2), and (b)(3) of the Federal Rules of Civil Procedure; direct that reasonable notice of this

action, as provided by Rule 23(c)(2), be provided to the Class; and declare Plaintiffs as the representatives of the Class;

[B] Enter joint and several judgments against the Defendants and in favor of Plaintiffs and the Class;

[C] Award the Class damages (*i.e.*, three times overcharges) in an amount to be determined at trial;

[D] Order disgorgement in the amount by which Defendants' ill-gotten gains exceed the treble damages awarded in this case;

[E] Grant permanent injunctive relief pursuant to § 16 of the Clayton Act to remedy the ongoing anticompetitive effects of Teva's unlawful conduct;

[F] Award Plaintiffs and the Class their costs of suit, including reasonable attorneys' fees as provided by law; and

[G] Award such further and additional relief as the case may require and the Court may deem just and proper under the circumstances.

XIII. JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiffs, on behalf of themselves and the proposed Class, demand a trial by jury on all issues so triable.

Dated: March 7, 2022

Respectfully submitted,

/s/James E. Cecchi

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